Development of a Smartphone-enabled hypertension and diabetes management package to facilitate evidence-based care delivery in primary healthcare facilities in India: A formative research to inform intervention design

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DECLARATION OF OWN WORK

I, AJAY VAMADEVAN SARALA, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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Abstract

Background

Hypertension and diabetes have become a major public health challenge in India. This research work aims to develop a feasible and scalable intervention for hypertension and diabetes, tailored to primary care settings in India.

Objectives

- To conduct a healthcare facility assessment to inform the development of a Smartphone-enabled intervention package for hypertension and diabetes at primary healthcare facilities in India
- To pilot the Smartphone-enabled hypertension and diabetes intervention package at primary healthcare facilities in India in order to identify the barriers, synergies and health system strengthening requirements for the feasibility and scalability of such an intervention.

Methodology

This research work was carried out in five Community Health Centres (CHCs) in Solan, Himachal Pradesh. The implementation and evaluation of the piloting, guided by a conceptual framework[1], was carried out using mixed methods, following implementation science principles.

[1] Fleuren M, Wiefferink K, Paulussen T. Determinants of innovation within health care organizations: literature review and Delphi study. Int J Qual Health Care 2004;16:107–23

Results

In this research work, a six component intervention was developed comprising a Nurse Care Coordinator (NCC), a structured training programme, clinical management guidelines, a Smartphone-based clinical decision-support system, counselling services and follow-up plan for patients. During piloting, NCCs detected that 37% of the out-patient clinic attendees had hypertension/diabetes. At three months of follow-up, systolic blood pressure had a mean reduction of 10.9+/-13.1 mmHg ($p<0.001$) in 2974 participants while fasting glucose level had a mean reduction of 26.4+/-49.0 mg/dl ($p<0.001$) in 717 subjects.

Discussion

This research work demonstrated that a six component intervention for hypertension and diabetes care is feasible. However, barriers such as inadequate manpower, insufficient drug supply and inadequate lab facilities need to be addressed for optimal intervention delivery.

Conclusion

A Smartphone decision-support-enabled, NCC-facilitated intervention for hypertension and diabetes is feasible for primary care settings in India.

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Acronyms

ACE-Inhibitor: Angiotensin Converting-enzyme Inhibitor
AIIMS: All India Institute of Medical Sciences
ARB: Angiotensin Receptor Blocker
BMO: Block Medical Officer
CCDC: Centre for Chronic Disease Control
CDSS: Computerized Decision Support System
CG: Control Group
CHC: Community Health Centers
CME: Continuing Medical Education
CMO: Chief Medical Officer
CVD: Cardiovascular diseases
DBP: Diastolic Blood Pressure
DSS: Decision Support System
ECG: Electro Cardio Graph
EG: Experimental Group
EMR: Electronic Medical Record
GNM: General Nursing & Midwifery
HbA1c: Glycaeted Haemoglobin A1c
HCO: Health Care Organisation
HFA: Health Facility Assessment
HIV/AIDs: Human Immunodeficiency Virus / Acquired Immune deficiency syndrome
HLEG on UHC: High Level Expert Group Report on Universal Health Coverage for India
ICCC: Innovative Care for Chronic Conditions
ICMR: Indian Council for Medical Research
IDF: International Diabetes Federation
IDI: In-depth Interviews
IGMC: Indira Gandhi Medical College
IPD: In-patient Department
IPHS: Indian Public Health Standards
KFT: Kidney Function Test
LDL: Low-density lipoprotein
LFT: Liver Function Test
LMICs: Low and Middle Income Countries
MACE: Major Adverse Cardiovascular Events
MCH: Maternal and Child Health
MeSH: Medical Subject Headings
MI: Myocardial Infarction
MP: Medication Prescription
MRC: Medical Research Council

NCC: Nurse Care Coordinator
NCD: Non-Communicable Diseases

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Thesis Outline

This thesis is assembled in four sections (sections A to D). The sections are further sub-divided into chapters, comprising a total of ten chapters. Section A contains three chapters. Chapter 1 introduces the problem and elaborates the rationale for this PhD work, which aims to develop a feasible and scalable intervention for hypertension and diabetes, tailored to primary care settings in India. Chapter 2 elaborates on the current status of hypertension and diabetes care in India and the barriers to evidence-based care and, finally, proposes a stepwise approach to develop the intervention. Chapter 3 contains two reviews: a) Systematic review of nurse-delivered interventions on hypertension and Type 2 Diabetes Mellitus in primary care settings; and b) Systematic review on the application of Smartphone/handheld device-based decision-support tools for chronic disease care interventions. These reviews were carried out to derive inputs for developing the intervention.

Section B comprising of just Chapter 4, describes the conceptual framework followed in the development of the intervention and briefly describes the overall methodology.

Section C is sub-divided into four chapters, which elaborate the results from this PhD work. Each chapter narrates the sequential phases through which the intervention was developed and evaluated. Results from the design phase of the intervention are presented in Chapter 5. This chapter presents: a) the detailed methodology followed in the needs assessment exercise carried out at the healthcare facilities; b) results from the needs assessment exercise; and c) discussion of the results. Chapter 6 elaborates the entire process in the formation of a basic structure of the intervention package using the inputs from the needs assessment exercise. Chapter 7 details the evaluation of the adoption stage of the

intervention at the healthcare facilities, while Chapter 8 presents evaluation of the implementation stage of the intervention at the health facilities, with a detailed methodology used for this stage, and discusses the results.

Section D has two chapters. Discussion of the overall findings of this PhD work is presented in Chapter 9 and the conclusion and recommendations are narrated in Chapter 10.

SECTION A

Chapter 1: Introduction and rationale for the PhD work

1.1 Hypertension and diabetes: a major public health challenge in India and the need to strengthen the primary care system

Non-communicable diseases (NCD) accounted for 53.5% of all deaths and were the leading cause of death in India in 2010 [1]. Among deaths due to NCD, cardiovascular diseases (CVD) accounted for the largest proportion (40 %). Even in rural India, chronic NCD are the leading cause of death (32 %) [2]. Projection estimates from the World Health Organisation (WHO) have shown that, by the year 2030, CVD will emerge as the main cause of death (36 %) in India, occurring at a comparatively younger age and at a lower risk factor threshold among Indians [3]. The losses due to premature death due to heart disease, stroke and diabetes are projected to increase cumulatively, with India standing to lose 237 billion dollars in national income during the decade 2005-2015 [4].

Hypertension and diabetes are major risk factors for cardiovascular diseases. Moreover, these two conditions co-exist and 40-60% of people with diabetes are reported to have hypertension as a comorbidity [5, 6]. Pooled estimates of various cross-sectional surveys in India have found that hypertension is prevalent in 25% urban and 10% rural adult subjects in India[7]. The WHO Atlas reports a rise in mean levels of systolic blood pressure among urban men aged 40–49 years (from 120.4 mmHg to 130 mmHg) during the period 1942 - 1997 [8]. A more recent systematic review of 48 studies carried out in various regions in India over the last few decades has reported a significant positive trend for the prevalence of hypertension by region and gender [9]. Further, Kearney, et al. estimate that the number of persons with hypertension in India will rise from 118.2 million in 2000 to 213.5 million

in 2025 [10]. The population growth expected during this period is only 39% (from 1 billion to 1.39 billion), as against an 80% increase in the number of persons in India with high blood pressure.

Similarly, studies carried out in the past two decades employing standardised methodologies show that the prevalence of diabetes is increasing in both urban and rural India, with estimates varying between 5 to 15 % in urban populations, 4 to 6 % in semi-urban populations and 2 to 5 % in rural populations [11, 12]. A recent large nationwide study - The ICMR-INDIAB study - covering 13,055 subjects in three states and one Union Territory reported that prevalence of diabetes varies across states in India. The prevalence of diabetes was 10.4% in Tamil Nadu, 8.4% in Maharashtra, 5.3% in Jharkhand and 13.6% in Chandigarh. Based on these figures, it is estimated that in India there are currently 62.4 million people with Type 2 diabetes and 77 million people with pre-diabetes [13]. The International Diabetes Federation (IDF) also provides similar figures for the year 2013, with an overall prevalence of 8.6 % (equivalent to 65.1 million people) in the age group of 20-79 years, which is expected to rise to 10.5 % by 2035 (equivalent to 109 million people)[14]. The prevalence of diabetes is increasing, even among the marginalised and the poor. In metro cities such as Chennai, the prevalence of diabetes is reported to be similar among low-income and middle-income groups [15]. In special groups, such as industrial population, a reversal of the socioeconomic gradient has been observed with a higher prevalence of diabetes among the poor compared to affluent groups [16].

Although hypertension and diabetes have emerged as a major public health challenge, a dedicated public health programme – the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) - was launched only

very recently, in 2008. Further, out of the planned 100 Districts in 21 States, dedicated NCD clinics, which are envisaged in the programme, had only been started in 41 district hospitals and 16 Community Health Centres (CHCs) by the end of 2012 [17]. Moreover, the programme will not cover the entire 627 districts until 2018. Thus, there are inadequacies in infrastructure to support hypertension and diabetes care in primary care settings in the majority of the districts.

The gaps in primary healthcare services, such as absence of opportunistic screening for hypertension and diabetes, and the insufficient use of clinical guidelines for evidence-based care delivery, are a major concern. For example, even in Kerala (a south Indian state with high literacy, and a better performing health system) among people with hypertension, only 37% were aware about their hypertension status, 27% sought medical care and 9% subjects had their blood pressure under control [18]. In contrast, 72% of the people with diabetes were aware of their condition and two thirds (68%) of such subjects were on medications, while only 22% of the subjects were able to effectively control their glycaemic level [18]. Another cross-sectional survey conducted in three villages of Himachal Pradesh (a north Indian state) involving 1092 participants, found that more than a third of the adult population (36%) had hypertension, with a higher prevalence among men (40%) than women (33%). In this group, only a fifth (22%) of the subjects with hypertension were aware of their disease status, out of which only one-fifth (20%) had their blood pressure under control [19]. Similar results have been reported from Tamil Nadu [20], Maharashtra [21], Haryana [22] and the Indian industrial population [23]. Thus, although hypertension and diabetes can be detected with simple diagnostic measures, even by a non-physician healthcare workforce at primary care, and are amenable to interventions, the healthcare

system in India fails to provide adequate healthcare services to a large majority of the population.

Recognising the importance of controlling NCDs for promoting global health, the WHO has advocated that the approach at primary care level for tackling NCDs is to prioritise identifying and treating people at high risk of NCDs, or those with already established disease, which has the potential to avert millions of deaths in the short term [24–27]. Further, this approach was identified by WHO as one of the best buys for NCDs in its global status report on NCDs for the year 2010 [27]. The Lancet Series on *'India: Towards Universal Coverage 3',* indicated that although there exists a range of cost-effective primary and secondary prevention strategies for chronic diseases, their coverage is generally low, especially for poor and rural populations [26]. These include extremely cost-effective (<INR4400 [US$100] per DALY averted) interventions, such as preventive drug treatment for high blood pressure (systolic blood pressure >160 mm Hg).

Given this background, it is important to develop a feasible and scalable intervention for hypertension and diabetes, tailored to primary care settings in India, which is the aim of this research work. In order to develop such an intervention, it is important to review the literature on the current state of care delivery and the barriers to evidence-based management of hypertension and diabetes at primary care levels in India, which is described in the next chapter (Chapter 2).

Chapter 2: Current state of, and barriers to, evidence-based care for hypertension and diabetes care in India

2.1 Current state of hypertension and diabetes care in India

There are a very limited number of studies that have looked at the practice patterns and quality of hypertension and diabetes care in India. A cross-sectional survey of people with diabetes, carried out in four metro cities of India - Mumbai, Delhi, Calcutta and Chennai - and four mini metros - Ahmedabad, Lucknow, Patna and Cochin – found that almost a third of the patients (31%) were treated by general practitioner (with basic medical qualification), while the remaining group were catered for by specialist physicians trained in medicine (33%) and diabetologists (36%), respectively [28]. In this urban group, close to half of patients (48%) were on oral drugs alone, 30% of the patients were on insulin, and the remaining (22%) were on a combination of insulin and oral drugs [28]. Even in this urban population, almost 40% of the subjects were unable to identify the importance of fasting blood glucose level and 34% of the subjects were unsure of the post-prandial value that ensures good glycaemic control. Further, only 10% of patients participated in any education programme on diabetes and only 30% received any booklet or information material from their care providers. Another community-based cross-sectional survey, carried out among people with diabetes in Kerala, found that 60% of the subjects had HbA1c level >7% while 26.4% had HbA1c level >9% [29]. Treatment of comorbidities such as hypertension (29%) and dyslipidaemia (5%) were very low in these subjects with only limited attention given to dietary counselling [29].

Adherence to evidence-based, clinical management of hypertension and diabetes is critical to ensure quality of care. However, poor quality of diabetes care has been reported, even in secondary and tertiary care hospitals, by the DEDICOM [30] and DiabCare Asia [31] surveys. The DEDICOM survey, which was carried out among patients with diabetes from the middle- and high-income group population of Delhi, found that only 13% of the patients had HbA1c estimation and 16.2% had had a dilated eye examination in the preceding year of the survey. Further, 42% had an HbA1c value >8%, 40.6% had low density lipoprotein (LDL) cholesterol level >130 mg/dl and 63.2% had blood pressure levels >140/90 mmHg. The DIABCARE Asia study, which was conducted among people with diabetes treated at tertiary diabetes care facilities in Indian cities, found that approximately half of patients had poor control (HbA1c > 2% points above upper limit of normal and fasting blood glucose > 139 mg/dl) [32] and more than half of patients (54%) had severe late complications, in addition to high occurrence of associated hyperlipidaemia. Only four percent of patients from these hospitals were reported on diet therapy, 53.9% were receiving oral hypoglycaemic agents (OHAs), 22% were receiving insulin and 19.8% a combination of insulin and OHAs. The 'A1chieve study', which reported the baseline profile of 20,554 Type 2 Diabetes Mellitus patients in India, found that the mean HbA1c was 9.2% in people who were initiated on or switched to insulin analogues, alone or in combination with oral hypoglycaemic agents. This clearly indicated sub-optimal use of insulin in India as a result of clinical inertia. Further, there were high levels of both macrovascular and microvascular complications in this group due to poor glycaemic control. The most common complication was neuropathy (25%) followed by cardiovascular (23.6%), renal (21.1%) and eye (16.6%) complications [33].

Reports on quality of hypertension care in India are scarce, although multiple studies have shown that that the 'rule of halves' applies for hypertension care in India, where detection, treatment and control of hypertension remain inadequate, as only half of adult population with hypertension were diagnosed, only half of those diagnosed were treated and only half of those treated were well controlled [34, 35]. According to the PURE Study, a multi-country study that compared prevalence, awareness and control of hypertension across several countries reported that India, Bangladesh, Pakistan and Zimbabwe together had only 5.1% of the subjects on treatment for hypertension using two or more blood pressure lowering medications, as compared to 38.9% in high-income countries, 30.1% in upper-middle income countries and 38.3% in other lower-middle income countries[36]. Hypertension care, even in established cardiovascular diseases cases, has been sub-optimal. A study conducted during 2003-04, among 134 primary care physicians selected from 50 cities in India, to assess the management of secondary prevention of coronary artery diseases has highlighted that hypertension was untreated in 33% of the cases and, of those under treatment, 23.7% received drugs other than beta-blockers or ACE-Inhibitors [37]. Moreover, the use of Aspirin (82.5%), beta-blockers (53.0%), ACE-Inhibitors (15.5%) and statins (69.0%) was sub-optimal for the management of secondary prevention of coronary artery diseases [37]. Another recent large prescription pattern survey in the state of Rajasthan, carried out during 2007 – 2008, reported deviation in the prescription of four classes of recommended medications (Aspirin, beta-blockers, ACE-Inhibitors and statins) for people with chronic stable angina or survivors of acute coronary syndromes for the secondary prevention of coronary heart diseases [38]. Even at tertiary care hospital level, the recommended multiple therapy was observed only in 54% of the prescriptions, while

prescriptions of tertiary level specialists (44%), secondary care physicians (28%) and primary care physicians (7%) had a lower adherence to recommended multiple therapy [38]. Similar reports on insufficient use of evidence-based medicine for the management of acute coronary syndrome have been documented by the OASIS registry [39] and the CREATE registry [40], even in tertiary care settings. Thus, implementation of evidence-based management for diabetes and hypertension is far from optimal at all levels of healthcare in India.

2.2 Barriers to evidence-based management of hypertension and diabetes in primary healthcare settings

Despite the availability of proven methods for detection, pharmacological and lifestyle management of hypertension and diabetes, several barriers exist at the healthcare provider level in delivering evidence-based care. These include insufficient screening activities [41]; insufficient importance given to hypertension/diabetes care [37]; uncertainty regarding when and how to implement lifestyle and pharmacological interventions [41–43]; failure of the health system in enforcing standards of care resulting from lack of consensus in diagnosis, management and follow-up [30, 38, 40]; failure to choose appropriate therapeutic options and reluctance to modify the regimen when treatment goals are not met [41]; poor follow-up of patients [41]; failure to motivate and educate patients [29, 41]; psychological barriers in initiating costly medicines such as insulin [29]; insufficient physician time [44]; lack of facilities and medicine supply, [45, 46]. A systematic review to determine the effectiveness of educational and organisational strategies used to improve control of blood pressure has found that, in addition to addressing each of these barriers, effective delivery of interventions in primary care settings requires a systematic organised

approach, by incorporating a regular review of high risk subjects (through follow-up and reminders) with a willingness to intensify drug treatment, if required, when management goals are not being met [47]. In order to further understand various barriers to hypertension and diabetes care specific to an Indian setting, a literature review was carried out to identify barriers at various levels. The results from the review are summarised below:

2.2.1 Patient level factors

Knowledge about hypertension and diabetes is an important factor that acts as a barrier to early detection and care. Knowledge about hypertension was reported to be as low as 22% in Himachal Pradesh to 61% in Kerala, although both states have high literacy rates [19, 48]. Awareness about complications among people with hypertension was also low. Only a quarter of persons with hypertension [49, 50] were aware of its cerebrovascular and cardiovascular complications, while only fewer than 10% were aware of retinopathy and nephropathy complications [49]. By contrast, with regard to diabetes, only a fourth of the adult population of was unaware of diabetes as a medical condition, as reported from a study carried out in Tamil Nadu[51]. However, the knowledge of complications and other long-term consequences of diabetes was reported to be poor, even in people with diabetes mellitus. For example, studies conducted among patients in the regions of Kolkata, Saurashtra and Chennai reported that fewer than half the patients (27-48%) had adequate knowledge of the complications of diabetes [51–53].

Socio-economic position is reported to play an important role in the detection and self-care of hypertension and diabetes. A community-based study in Bangalore reported that, among high-income groups, diabetes was diagnosed earlier (mean difference of 4.7 years) compared to lower socio-economic groups [54]. Monitoring of blood sugar levels was also

reported to be significantly better among high-income groups (odds ratio: 2.7; CI: 1.4-5.2) from a study carried out in Vellore, Tamil Nadu [55]. In addition, ***educational status*** was also found to be directly associated with awareness of these health condition and seeking healthcare [48, 56]. ***Poor adherence of patients to medications has*** been reported by studies carried out in Delhi and Kerala as another barrier in achieving adequate control of hypertension and diabetes [57, 58].

Hospital-based studies have reported that fewer than half of the patients with diabetes were found to be adhering to medication schedules in Kolkata (32.2%) and Delhi (47.7%). With respect to hypertension, compliance to anti-hypertensive medication schedules varied from 32-63% [53, 59]. Socio-economic position also had a role in compliance. Compliance was as high as 80% among people with diabetes in middle and high-income groups in Delhi [60]. The major reason cited by patients for non-compliance, as reported in these studies, was financial constraints [53, 59, 61]. Inability to carry out physical exercises and adoption of traditional medicines – mostly unproven practices promoted by divine healers- were also cited as reasons for non-compliance.

Age and attitude of patients also play a role in achieving better hypertension/diabetes control. Elderly patients often require pharmacological treatment to achieve adequate control of hypertension/diabetes due to the prolonged course of the disease. Only very few elderly subjects (aged more than 60 years) with hypertension (3.2%), participating in a study carried out in Delhi, were found to be able control their blood pressure with non-pharmacological interventions alone [62]. Attitudes towards various measures in management of diabetes also act as barriers in achieving adequate control. For example, more than half of the people with diabetes (51.4%) who participated in a study in the

Saurashtra region of Gujarat perceived that drugs were more important than adopting a healthy lifestyle - particularly practicing regular exercises - in the management of diabetes.

2.2.2 Provider level factors

Several barriers operate at the level of healthcare providers in offering quality healthcare services for hypertension and diabetes. ***Insufficient time is spent by doctors*** explaining to patients the management and lifestyle changes to be made to achieve adequate control of the conditions. Shah, et al., in 2009, reported that doctors spent less than five minutes with 50% of the patients with diabetes [52]. Moreover, only 34% of patients reported that their doctor advised them about the importance of self-management [63]. As a result, a large majority of patients with diabetes (60%) did not know the long-term complications of diabetes. The overcrowding of hospitals is a reason cited for insufficient time spent by the doctors with patients. Given that the main source of health information related to chronic diseases, such as hypertension and diabetes for patients, was healthcare professionals (67.15%), the limited time available for doctors to educate patients was found to be a major barrier for delivery of quality care [52, 64–66].

Insufficient use of guidelines was reported by multiple studies. A prescription audit study carried out in a primary care setting in Haryana reported the underutilising of combination drugs for hypertension (38.9%) and greater preference of physicians for monotherapy (57.8%) [67]. Further, the DAWN study - a multi-country study that compared management practices for diabetes - found that physicians in India delayed the initiation of insulin therapy more than other countries [68]. Similarly, the use of diagnostics tests such as HbA1c – which aid in monitoring long-term glycaemic levels - in the management of

diabetes mellitus was also reported to be lower. Hospital-based patient surveys have reported that fewer than 7% of patients have undergone HbA1c investigations for diabetes monitoring [61, 66]. In addition, insufficient monitoring of complications was a major concern. Only a third of the patients with diabetes had their feet examined by their physician [52], 16% of patients had their eyes examined and 32% of patients had their serum cholesterol level assessed [60]. A survey among diabetologists in India, which explored their opinion on evidence-based management of diabetes, identified poor awareness among physicians (22.7%), limitations in the applicability of western guidelines to the Indian population (22.7%), financial constraints to patients (18.2%), individual patient variation (13.6%) and lack of patient compliance (9.0%) as important barriers to the practice of guidelines [69]. Various mechanisms suggested by the diabetologists for ensuring evidence-based practice were educating physicians on evidence-based management (29%), continuing medical education sessions (24%) and provision of incentives and motivation for physicians (16%) [69].

The acute shortage of trained manpower, especially skilled specialists such as endocrinologists and diabetologists, even at tertiary care government health facilities, and lack of support staff such as dieticians [52] is a major health system barrier for diabetes/hypertension care. Further, the recently launched National Program for Cancer, Diabetes, Cardiovascular diseases and Stroke, which aims to establish NCD clinics in primary care settings, covers only 100 districts of India. ***Limited availability of even inexpensive medications,*** such as Sulphonylureas and Metformin, at the government hospitals was another barrier for healthcare. The availability of drugs, assessed in five states in India, found that availability of Glibenclamide (a Sulphonylurea group medicine) –

one of the low-cost generic oral hypoglycaemic agents – at government hospitals ranged between 3% in West Bengal to 100% in Karnataka [70].

Access to care was also cited as a barrier for healthcare. Control of blood pressure in Himachal Pradesh has been reported to be high in urban areas that have better access to healthcare as compared to difficult hilly terrain in the state (16.6% vs. 1%) [19]. Similar findings were observed in a multi-site study when several urban locations were compared with rural sites (5.9% vs. 1.3%) in India [71].

In summary, there exist several barriers at the level of providers and patients in screening, diagnosis, implementation of evidence-based guidelines, intensification and follow-up of treatment regimens, and coordination of various aspects of hypertension and diabetes care in primary care settings in India.

2.3 Gaps in hypertension and diabetes care delivery: a proposed solution

Although the Government of India is contemplating the expansion of the on-going pilot National Programme for the Prevention and Control of Cancer, Diabetes, Cardiovascular diseases and Stroke (NPCDCS) to the entire nation in another five years, along with additional measures such as increase in the overall government spending to ensure free supply of medicines for all citizens and a strengthening of healthcare infrastructure in the nation [72], there is a clear need for carefully developed interventions that maximize the efficient use of scarce resources at the public healthcare facilities where case management of hypertension and diabetes has been relatively poor. A new intervention, comprising opportunistic screening as well as case management of the two ailments, needs to be

delivered at primary care level through a trained health cadre equipped with clinical decision-support tools to ensure quality of care. However, any newly proposed intervention requires sufficient evidence to position it as a solution to address the gaps in care delivery.

Hence, in this PhD work, a structured approach was used for developing an intervention in a stepwise manner:

1. Review of evidence on nurse-delivered interventions for hypertension and diabetes care in primary care settings. In India, the healthcare team comprises of, predominantly, doctors, nurses and health workers. This review focuses on nurse-delivered interventions because, in a typical government healthcare setting, the nurse cadre is uniquely positioned to carry out multiple tasks such as opportunistic screening, clinical assessment and behavioural counselling of patients. Other care providers, such as health workers, are engaged in community-based care delivery rather than in a hospital setting. Further, the number of other care providers, such as pharmacists or nutritionists, in a government health facility is very limited and, therefore, reviewing nurse-delivered interventions was chosen. Moreover, the NPCDCS envisages appointing two nurses at the NCD clinics of all Community Health Centres in the country.
2. Review of evidence on Smartphone-based clinical decision-support tools (DSS) for evidence-based management. The choice of reviewing a Smartphone-based clinical decision-support system was taken for the following reasons. Compared with paper-based decision-support tools, an electronic decision-support system has several advantages. It is easy to electronically update the ‘ever evolving’ clinical guidelines embedded in the decision-support software installed in Smartphones linked to a central

server. In comparison with a paper-based tool, this feature reduces the time lag in updating the healthcare team located at the rural and remote healthcare facilities about changes in guidelines. Further, Smartphone DSS is capable of creating electronic health records, which can be easily retrieved during follow-up visits and, thereby, enhance continuity of care. Moreover, a wide range of mobile technologies have been developed and continue to be devised for diagnosis and personal monitoring of chronic conditions such as hypertension, diabetes, asthma and chronic obstructive pulmonary disease[73]. Health systems are also switching to technology to improve the speed and accuracy of reporting systems. For example, many of the national health programmes in India, such as the Reproductive & Child Health Program, have started using mobile phone-based reporting systems at primary care level, while the Integrated Disease Surveillance Project relies on both an electronic computer-based system as well as short-messaging services for reporting [74]. Thus, an electronic DSS provides an opportunity for integrating into health information systems in future. Moreover, compared to computers, Smartphones are cheaper, portable, require much less power and come with built-in communication and internet capabilities.

3. Development of an intervention tailored to primary care systems in India through a needs assessment exercise
4. Piloting of the intervention to evaluate its feasibility, acceptability and scalability, which can be subsequently assessed for its effectiveness in a control trial

Chapter 3: Systematic reviews

This chapter contains two reviews: a) Systematic review on nurse-delivered interventions on hypertension and Type 2 Diabetes Mellitus in primary care settings; and b) Systematic review of Smartphone/handheld device-based decision-support tool-based interventions in chronic disease care. These reviews were carried out to derive inputs for developing the intervention.

3.1 Systematic review of nurse-delivered interventions on hypertension and Type 2 Diabetes Mellitus in primary care settings

3.1.1 Introduction

Achieving adequate coverage and access to chronic non-communicable disease care at a primary health care level is often a challenge in low and middle income countries (LMICs). The World Health Report 2006 advocated for delegation of some of the tasks, such as diagnostic and therapeutic function, from physicians to less-specialised, non-physician health cadres as a solution to this problem. Task-shifting/sharing has been a key element in successful scaling-up of HIV-programmes in several LMICs [75]. A Cochrane review that compared nurses and physicians in primary healthcare services provision found similar health outcomes for patients, process of care and resource utilisation or cost between the groups in studies carried out in developed nations [76]. The feasibility and utility of nurse-delivered hypertension and diabetes management at primary care level has also been demonstrated in the developing world, such as in Sub-Saharan Africa [77, 78]. In such

nurse-delivered interventions, the roles of nurses included patient evaluation, patient education, counselling, telephonic follow-up for medication adherence/review visits and so on. This review aims to identify the various roles that nurses played in the nurse-delivered intervention studies in hypertension and diabetes as well as to synthesise evidence on the effect of such interventions on patient outcomes in order to derive inputs for designing an intervention for hypertension and diabetes care in primary care settings in India.

3.1.2 Objective

To summarise the various roles of nurses in nurse-delivered interventions for the management of hypertension and Type 2 Diabetes Mellitus in primary healthcare and synthesise evidence on the effect of such interventions on patient outcomes.

3.1.3 Methodology

The review followed the guidelines of Cochrane Handbook for Systematic Reviews of Interventions and PRISMA guidelines for reporting the results [79].

Inclusion criteria

- Types of Participants

  The populations of interest were patients with hypertension and/or Type 2 Diabetes Mellitus, aged 18 years and over. Studies reporting chronic disease management with subgroup analysis for patients with hypertension and/or Type 2 Diabetes Mellitus were also included.

- Type of Interventions

- Nurse-delivered interventions, such as pharmacological therapy, case/care management, disease management programme, follow-up and referral, patient education, and medication adherence aimed at improving control of blood pressure and/or glycaemic control in patients with hypertension and or diabetes mellitus. Studies which included nurse-delivered care as co-interventions were also included.

- Outcomes: studies were included if they reported any one of the following outcomes:
  - Change in mean systolic blood pressure and/or mean diastolic blood pressure
  - Control of blood pressure/target achievement
  - Change in mean glycaeted haemoglobin level (HbA1c)
  - Control of glycaemic level/target achievement
- Settings: patients recruited from primary care facilities, diabetes/hypertension clinics, and out-patient departments/clinics of medical centres/hospitals.

Information sources

English language databases were searched for original investigations, including MEDLINE via Pubmed, EMBASE, OVID, CINAHL, PsycInfo and Cochrane CENTRAL. In addition, reference lists of all the papers and relevant reviews were manually searched for potentially relevant articles.

Study selection

The databases were searched using a strategy combining selected medical subject headings (MeSH) and free text terms relating to hypertension, Type 2 Diabetes Mellitus and nurse-delivered care. The search strategy was applied in the entire lists of database searched, with necessary changes in relevant vocabularies. The search results from the databases were imported into the Reference Manager 12.0 software. Two reviewers (myself and A. M. Chandrasekaran, a Research Fellow at the Centre for Chronic Disease Control, New Delhi) independently assessed the list of citations and abstracts. Differences were resolved by discussion.

Data collection process

Data were extracted from the full text papers retrieved using a structured template, which included data on the patients, intervention, type of study design, duration of the study, follow-up and the outcomes. No authors were contacted for any additional information.

Quality of individual studies

The included studies were assessed and reported based on their risk of bias in accordance with the guidelines of the Cochrane Handbook for Systematic Reviews of Interventions [79]. Use of scales for assessing the quality of trials or risk of bias is a simple method widely used. However Cochrane collaboration discourages the use of scales for assessing quality or risk of bias in trials citing reasons such as: 1) Lack of empirical evidence; 2) Difficulty in justifying the weights assigned to different items in a scale to generate a summary score; 3) Unreliable assessments of validity; and 4) Being less likely to be transparent to users of the review. Cochrane Collaboration currently recommends the use of Risk of Bias tool [79]. The Jadad scale is another commonly used in randomized controlled

trials related to pain research [80]. The Cochrane Collaboration discourages the use of the Jadad scale as well, due to its emphasis on reporting rather than conduct, and because it does not take allocation concealment into account. However, the Jadad scale was used in this review due to its simplicity for assessing the quality of trials and their risk of bias. Jadad scale has a maximum possible score of five (two points for descriptions of randomisation, two points for descriptions of double blinding and one point for descriptions of withdrawals) [80].

Summary measures

The summary measures used in this study were mean differences between the study groups and odds ratios (categorical variables) as reported. A random effects meta-analysis model was used to pool data to estimate the mean difference in outcome whenever sufficient data was available for outcome variable. The Cochrane Collaboration RevMan 5.3 software was used for pooling the data for meta-analysis [81].

Synthesis of results

The data were analysed quantitatively and qualitatively, discussing the effectiveness of the intervention for each outcome variable along with a brief description of the included studies.

Additional analysis

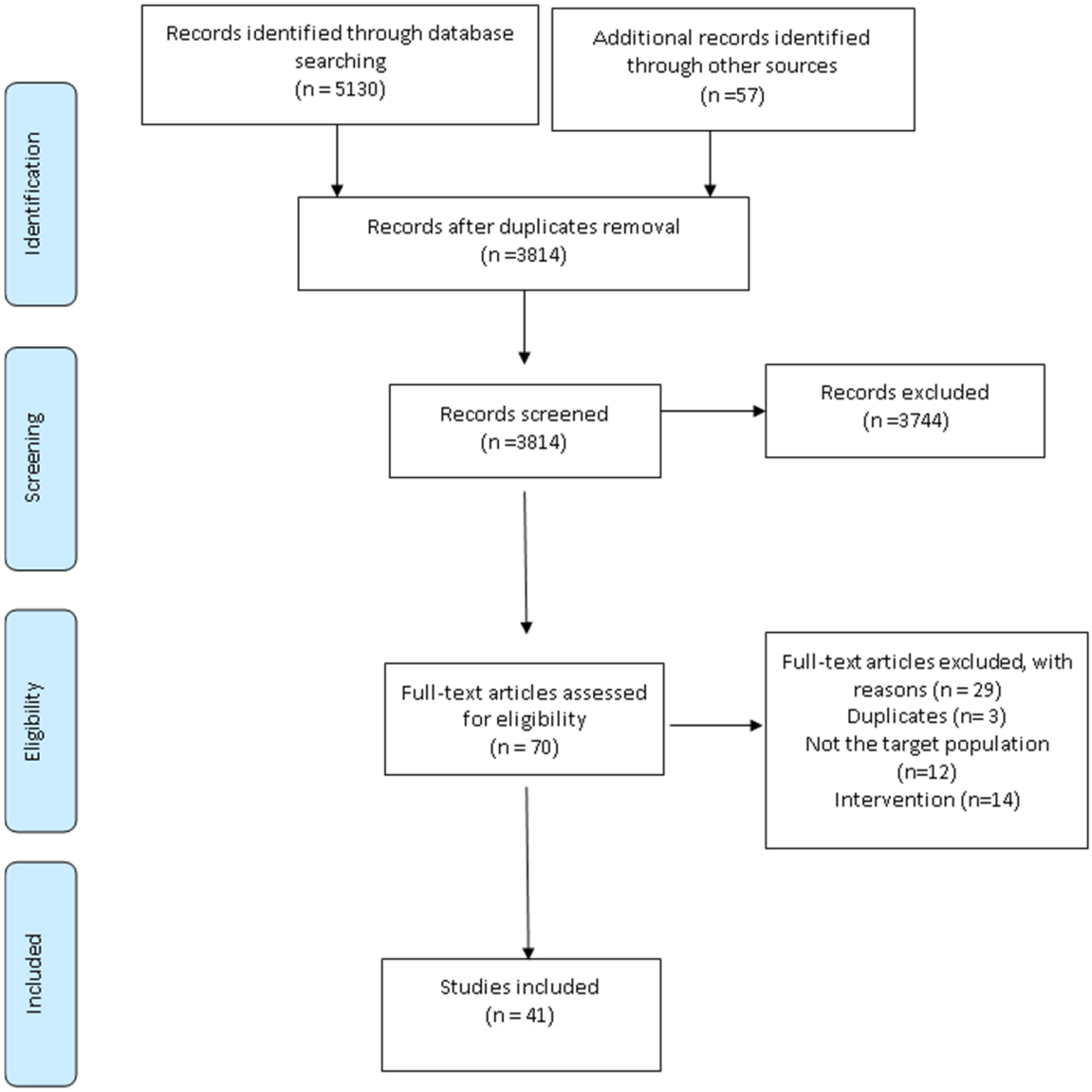
Meta-analysis was done and reported after assessing heterogeneity of studies.

3.1.4 Results

Study retrieval

The search strategy yielded 5135 publications from the databases and an additional 57 publications were found through manual searching of published reviews and trials. After removing duplicates, title screening and abstract screening, 70 publications potentially relevant for the review were retrieved. A total of 41 publications met all the inclusion criteria. Two full text papers could not be retrieved and, hence, the data were extracted from the abstracts. The study selection procedure is depicted in a flow diagram (see Figure 3.1).

Figure 3.1: Flow diagram for systematic review of the literature on nurse-delivered interventions for the management of hypertension and Type 2 Diabetes Mellitus



Reasons for excluding 3744 records from systematic review:

After duplicates removal, the title and abstract of all the articles were screened for their eligibility to be included in the review in accordance with the inclusion and exclusion criteria as described in the methodology. The abstracts were screened for PICO (Population, Intervention, Comparator and Outcome), study design (description in the abstract indicating whether the study was a randomized controlled trial) and the study setting (primary health care, tertiary care, in-patient care, community based) in order to select qualifying papers for review. While screening abstracts, care was taken not to miss any potential papers by going to full text whenever required. Articles were excluded only when there was evidence in the title or abstract, to conclude that, the paper was of not of interest. Following this rule 3744 articles were excluded through screening, which were not meeting the inclusion criteria.

Characteristics of included studies

The study reports were from 14 countries with the maximum number of studies (23 trials) carried out in the USA, followed by four in Canada. Only three studies were from low and middle income countries (China, Iran and Thailand) [82–84]. Eighteen trials [84–101] included only patients with Type 2 diabetes, while 14 trials [82, 83, 102–113] had only patients with hypertension. Six trials [114–119] had patients with both diabetes and hypertension and the remaining three trials [120–122] had patients with either Type 2 Diabetes Mellitus or hypertension.

In the selected studies, a total of 13,994 participants were included and the number of participants in the studies ranged between 51 [109] and 1665 [97]. Participant follow-up was for a minimum of two months [82, 112] and a maximum of 60 months [97]; in the majority of the studies (17 out of 41), the participants were followed for 12 months. Eight studies had longer duration (>12 months) of follow-up while one study [83] did not report information on the duration of the intervention. Six studies [90, 92, 98, 110, 118, 119] had predominantly male participants (>96.7% out of a total sample of 2503). The mean age of the study group ranged from 46 to 71 years. A brief description of the studies included [82–122] is given in Table 3.1.

Most of the trials had pre-defined protocols, which can be described as "disease management algorithms" and were the integral part of the interventions. In addition, almost all the studies reported patient education, support for medication adherence, monitoring of health status, provision of reminders for follow-up, screening and counselling for lifestyle changes as components of the interventions. The comparison group was 'usual care' in 22

studies, enhanced usual care in three studies and other interventions in the remaining 16 studies. The trials could be broadly grouped into four categories, with some studies overlapping the groups:

- Nurse practitioner-led care: interventions in which nurses provided pharmacotherapy at primary care level (17 studies) [84, 87, 91–93, 99, 102, 103, 106, 113–115, 117, 118, 120–122], independently or under supervision of a primary care physician.
- Telephone-mediated care: nurses contacted patients over the telephone for patient education, medication adherence support, monitoring health status, providing reminders for follow-up, counselling for lifestyle change (18 studies). [82, 84–86, 88, 90–93, 96, 98, 106, 108, 110, 111, 118, 119, 121]
- Team-based care: intervention led by a healthcare team involving nurses as a member along with other care provider members, such as pharmacists, dieticians or community health workers (six studies [83, 89, 91, 96, 116, 122])
- Technology-assisted interventions: nurse-delivered interventions involving the use of computerised decision-support system (CDSS) for patient management, or electronic medication adherence support, or automated algorithm based tele-education, or automated BP monitoring (six studies). [88, 92, 97, 106, 110, 119]

Roles of nurse

The roles described for nurses in the interventions attempted in the trials were heterogeneous in nature. The various roles of nurses included protocol/guidelines/algorithms-based medication prescription, patient evaluation (comprising history-taking, general physical and clinical examination and collection of

blood and urine samples), drug prescription, medication review, patient's record review, referral, facilitating compliance / adherence to medication, reinforcement, tele-monitoring/follow-up, patient education, lifestyle counselling (dietary modifications, physical activity promotion, tobacco cessation and limiting alcohol use), positive reinforcement, problem identification, home visits, educating and monitoring the use of automated blood pressure monitor/automated blood glucose meter and motivational interviewing (Figure 3.2). These roles could be broadly grouped as: a) Patient Assessment (PA); b) Patient Management (PM); c) Patient Education (PAED); and d) Medication Prescription (MP) based on protocols or guidelines (See Figure 3.2).

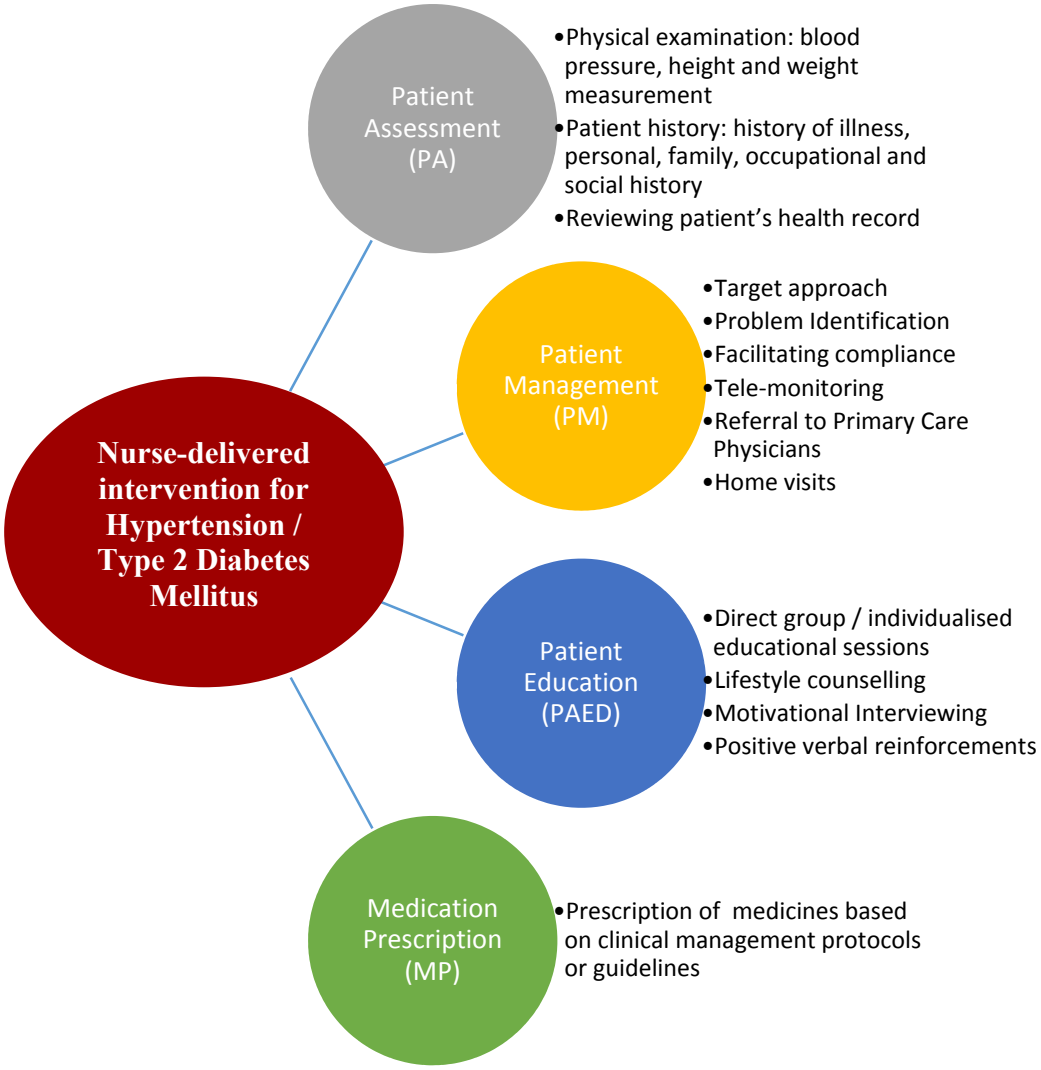
Patient assessment (PA) included conducting clinical examinations such as measuring blood pressure, measuring height and weight and taking patient history, including the history of illness, personal, family, occupational and social history, and reviewing the patient's health record. One or more combinations of these individual components were studied in 37 trials.

Patient management (PM) was the core of many of the interventions (reported as an intervention in 39 studies). PM encompassed problem identification in relation to adherence to medications or lifestyle advice, helping patients achieve target blood pressure and or HbA1c levels through medications, facilitating compliance, maintaining regular follow-up, with or without the use of telephone, referral of patients to the primary care physicians whenever necessary and conducting household visits for patient care.

Patient education (PAED) included direct educational sessions targeted at a group of diseased individuals or with individual patients, counselling the patients for lifestyle modifications and motivational interviews for educating the patients. One or more components of patient education were included as a part of intervention in 37 studies.

A total of 17 studies had Medication Prescription (MP) roles for nurses. In such studies, nurse practitioners had privileges to prescribe medicines to patients. The nurses prescribed medicines following clinical management protocols or guidelines which were part of the intervention.

Figure 3.2: Roles of nurses in nurse-delivered interventions



Effects of nurse-delivered interventions on blood pressure

Effect of nurse-delivered interventions on mean systolic blood pressure (SBP) and mean diastolic blood pressure (DBP) was reported in 32 and 28 trials, respectively, while 15 trials reported effect on achieving blood pressure targets as one of the outcomes.

The effect on mean systolic blood pressure

Change in SBP was reported as an outcome in 32 randomised control trials. This group of trials recruited a total of 11567 participants, randomising 5693 subjects in the experimental group (EG) and 5477 subjects in the control group (CG). One of the trials, which recruited 397 subjects, did not report group-wise participants. Data from 10883 participants (5259 in EG;,5043 in CG and 511 from two studies which did not report group-wise participants) were analysed [82, 83, 87, 91–101, 103–117, 119, 120, 122]. See Table 3.3 for details. Thirteen trials [82, 83, 103–113] were exclusively on adults with hypertension, while the remaining trials had participants who also had coexisting morbidity (i.e. Type 2 Diabetes Mellitus). Sixteen trials (6551 participants randomised and 6488 analysed) reported favourable effects on SBP while 16 studies (5016 participants randomised and 4395 analysed) reported no difference between the experimental and control groups. The mean Jadad score for the included studies was 2.74. Studies reporting positive effect size had a mean Jadad score of 3, while studies reporting no difference had a mean score of 2.5.

These trials were then further grouped into studies involving **nurses with and without drug prescription roles**. Out of thirteen trials in which nurses had a role in drug prescription, four trials (mean Jadad score: 2.75) reported a mean reduction of SBP ranging from 6.2 - 10 mmHg, whereas the remaining nine studies (mean Jadad score: 2.33) found no effect on blood pressure.

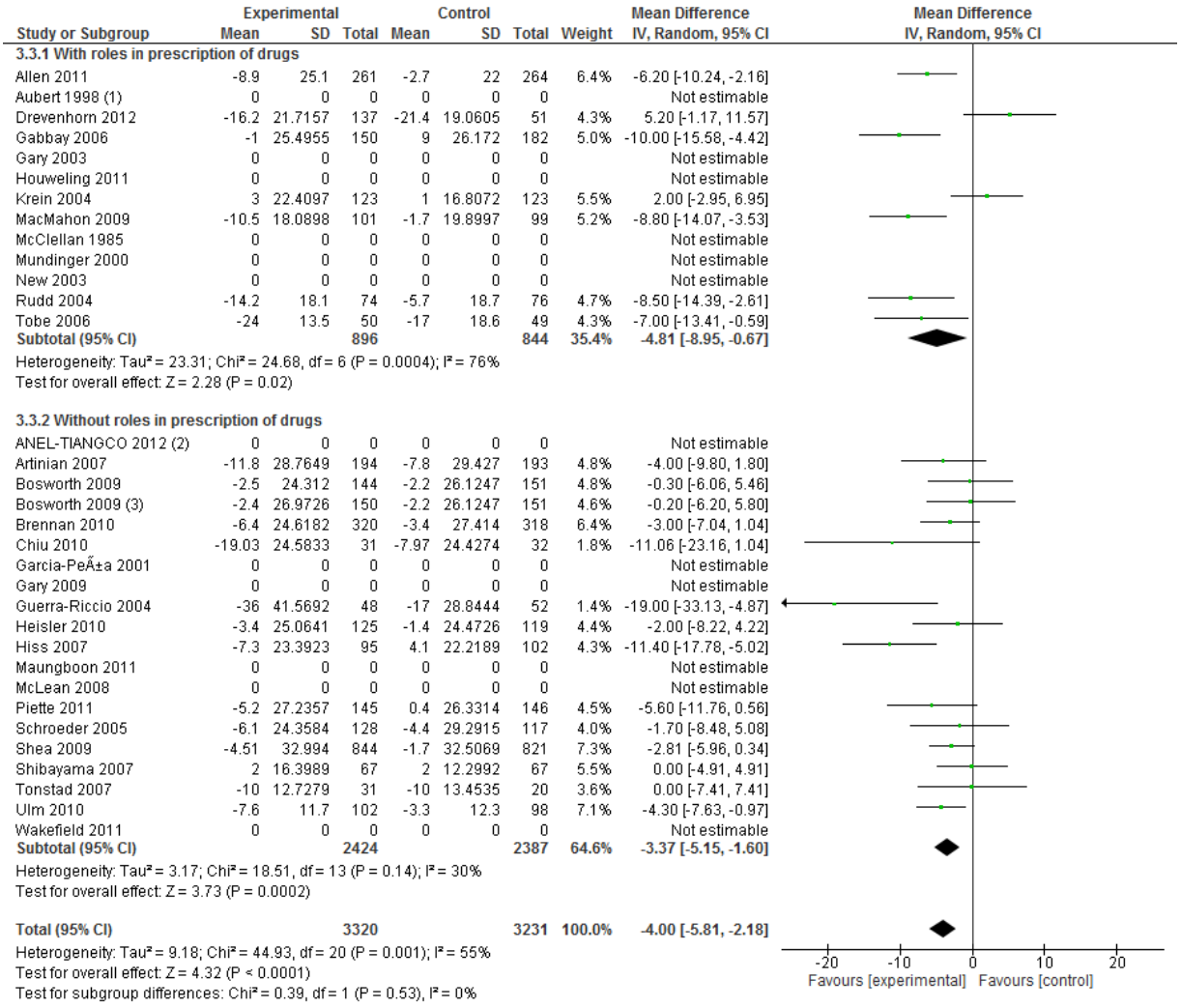
Seven trials reported sufficient data to carry out a meta-analysis and the results showed a significant decrease of -4.81 mmHg (-0.67 to -8.95 mmHg, random effects) of systolic

blood pressure in the intervention arm compared to the control arm (see Figure 3.3). However, the result was limited by the high heterogeneity of the included studies (I^2: 76%). The studies excluded did not report one or more of the key information essential for conducting meta-analysis such as: 1) Number of participants in each group; 2) Mean values of the outcome from both baseline and endline assessment; and 3) standard deviation or standard error of the mean values reported. The studies which failed to report any of these information were excluded from the meta-analysis. The included seven studies in the meta-analysis had a mean Jadad score of 2.6 while the excluded six studies had a mean score of 2.3.

Effect of nurse-delivered interventions (without drug prescription role for nurses) on mean systolic blood pressure was studied in 19 trials [82, 83, 94–98, 100, 101, 104, 105, 107–112, 116, 119]. Twelve trials (mean Jadad score: 2.67) reported significant favourable effects with a mean difference in systolic blood pressure ranging from -3 mm Hg to -19 mm Hg, whereas the remaining seven studies (mean Jadad score: 3.28) reported no difference between the groups. Thirteen trials reported sufficient data for a meta-analysis, which demonstrated a significant reduction in systolic blood pressure (3.37 mmHg; CI: -1.60 to -5.15 mmHg; random effects) in the intervention group compared to the control group (see Figure 3.3), with moderate heterogeneity (I^2: 30%) of studies. Further, one of the trials was a four arm study with two intervention arms i.e. with and without provider decision-support system for nurses and, hence, was added twice in the meta-analysis [110]. The mean Jadad scores were 3.0 and 2.8 for the 13 included and six excluded studies in the meta-analysis respectively.

Another meta-analysis was attempted using the difference in the endpoint systolic blood pressure as the outcome. In the meta-analysis, interventions with nurses having a role in drug prescription were found to have a significant reduction in systolic blood pressure (-3.26 mmHg; CI: -0.94 to -5.57 mmHg; random effects) and the included studies were less heterogeneous (I^2- 26%). The five included studies had a mean Jadad score of 2.4 while the excluded eight studies had a mean score of 2.5. Similarly, interventions without the roles for nurses in drug prescription component also had a significant effect in reducing systolic blood pressure (-2.42 mmHg; CI: -0.84 to -4.01 mmHg; random effects). However, included studies had moderate heterogeneity (I^2: 49%). The mean Jadad score for the included twelve studies were 2.9 while the eight excluded studies had a mean score of 3.3. See Figure 3.4.

Figure 3.3: Effect of nurse-delivered interventions on systolic blood pressure with and without roles in prescription of drugs.



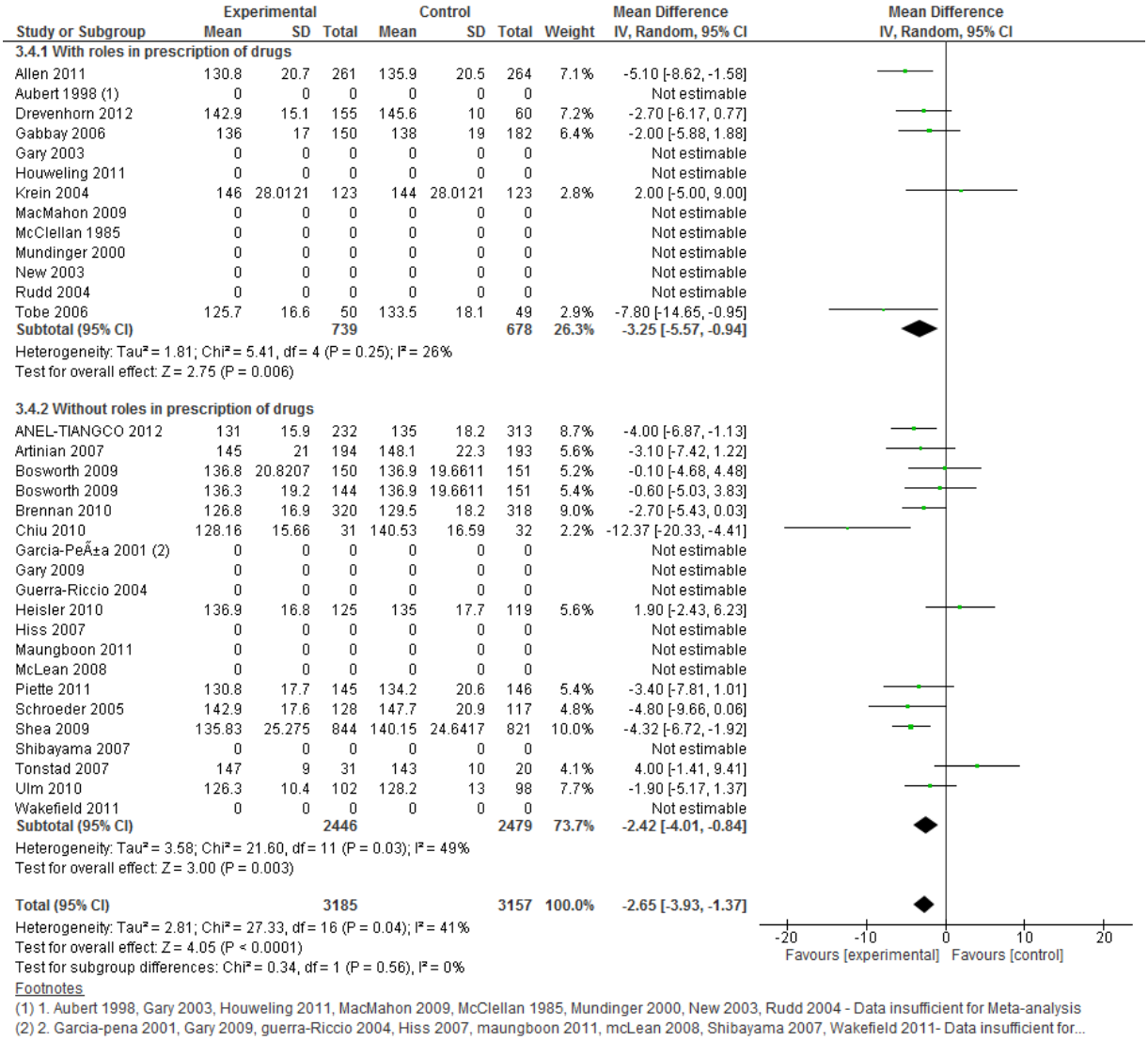
Footnotes

(1) 1. Aubert 1998, Gary 2003, Houweling 2011, McClellan 1985, Mundinger 2000, New 2003 - Data Insufficient for Meta-analysis.

(2) 2. Anel Tiangco 2012& Maungboon 2011 (Abstract Only), Garcia-Pena, Gary 2009, Mclean 2008, Wakefield 2011 - Data Insufficient for Meta-analysis

(3) 3. Bosworth HB, four arm study. Nurse CaRe intervention with and without provider decision support included for analysis.

Figure 3.4: Effect of nurse-delivered interventions on end point systolic blood pressure with and without roles in prescription of drugs.



Effect on mean diastolic blood pressure

Effect on mean diastolic blood pressure was reported in 28 trials [82, 83, 87, 91–96, 98–109, 111–115, 120, 122]. In this study group, a total of 9272 participants were randomised, of which 8763 participant data were analysed. Of the 28 trials, 12 trials had participants with hypertension alone while the remaining trials had participants with comorbid Type 2 Diabetes Mellitus. Ten trials (3512 participants randomised and 3382 analysed) reported favourable outcomes while the majority of the trials reported no significant difference between groups (5760 randomised and 5381 analysed). Mean Jadad scores for all the trials, studies reporting favourable effects and the trials reporting no difference, were 2.64, 2.45 and 2.76, respectively (Table 3.4).

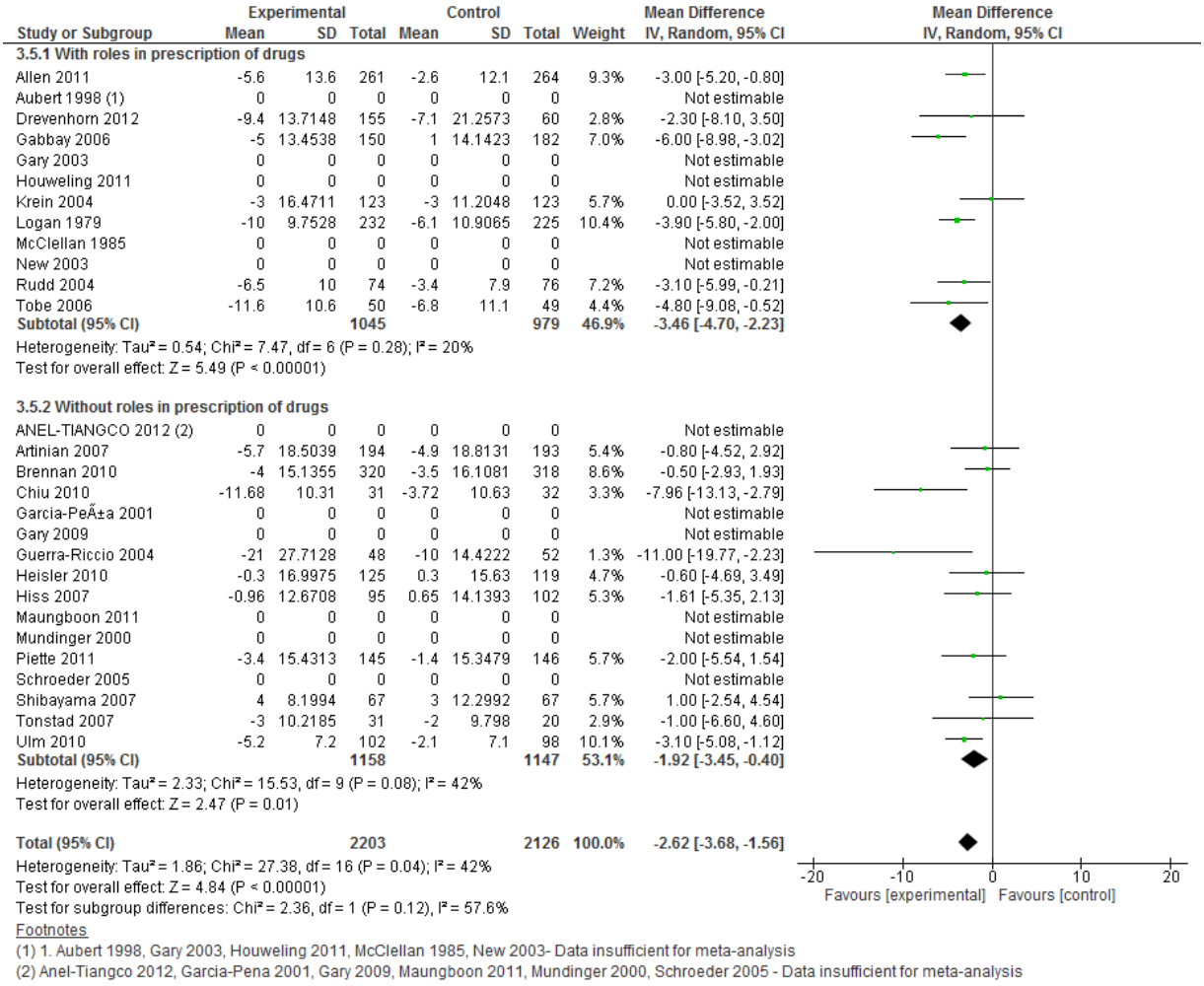
Interventions with roles for nurses in drug prescription reported beneficial effects on diastolic blood pressure (mean reduction range: -3.1 to -8 mmHg) in four trials [93, 106, 115, 122] (mean Jadad score: 2.75) while six trials (mean Jadad score: 2.5) reported no difference and one trial [102] (mean Jadad score: 3) did not report between group differences. Interventions without roles for nurses in drug prescriptions reported significant favourable effect (mean reduction ranged from -3 to -10 mm Hg) in five trials [82, 83, 104, 105, 112] (mean Jadad score: 2.5), while eleven trials did not.

Meta-analysis of trials demonstrated that reduction in diastolic blood pressure was higher (-3.41 mmHg; CI: - 2.234 to - 4.70 mmHg; I^2: 20%; random effects; seven trials) in nurse-delivered interventions with roles for nurses in drug prescription compared to interventions without such roles for nurses (-1.92 mmHg; CI: -0.40 to - 3.45; I^2: 42%; random effects; ten

studies). Ten trials (mean Jadad score: 2.8) reported sufficient data for including in meta-analysis while remaining six trials (mean Jadad score: 2.3) were excluded due to insufficient data in their reports. The results were limited by the heterogeneity of studies included in the meta-analysis (see Figure 3.5).

Meta-analysis of results from trials using endpoint diastolic blood pressure was also attempted, which showed similar reduction in diastolic blood pressure (-2.69 mmHg; CI: -1.03 to - 4.36 mmHg; I^2: 35%; random effects; four studies) in nurse-delivered intervention with roles in drug prescription, but not in interventions without roles for nurses in drug prescription (-0.04 mmHg; CI: -1.00 to 0.93 mmHg; I^2: 12%; random effects; eight studies). Eight trials (mean Jadad score: 3.0) reported sufficient data for including in meta-analysis while remaining eight trials (mean Jadad score: 2.3) were excluded due to insufficient data in their reports. See Figure 3.6 for details.

Figure 3.5: Effect of nurse-delivered interventions on diastolic blood pressure with and without roles for nurses in prescription of drugs.

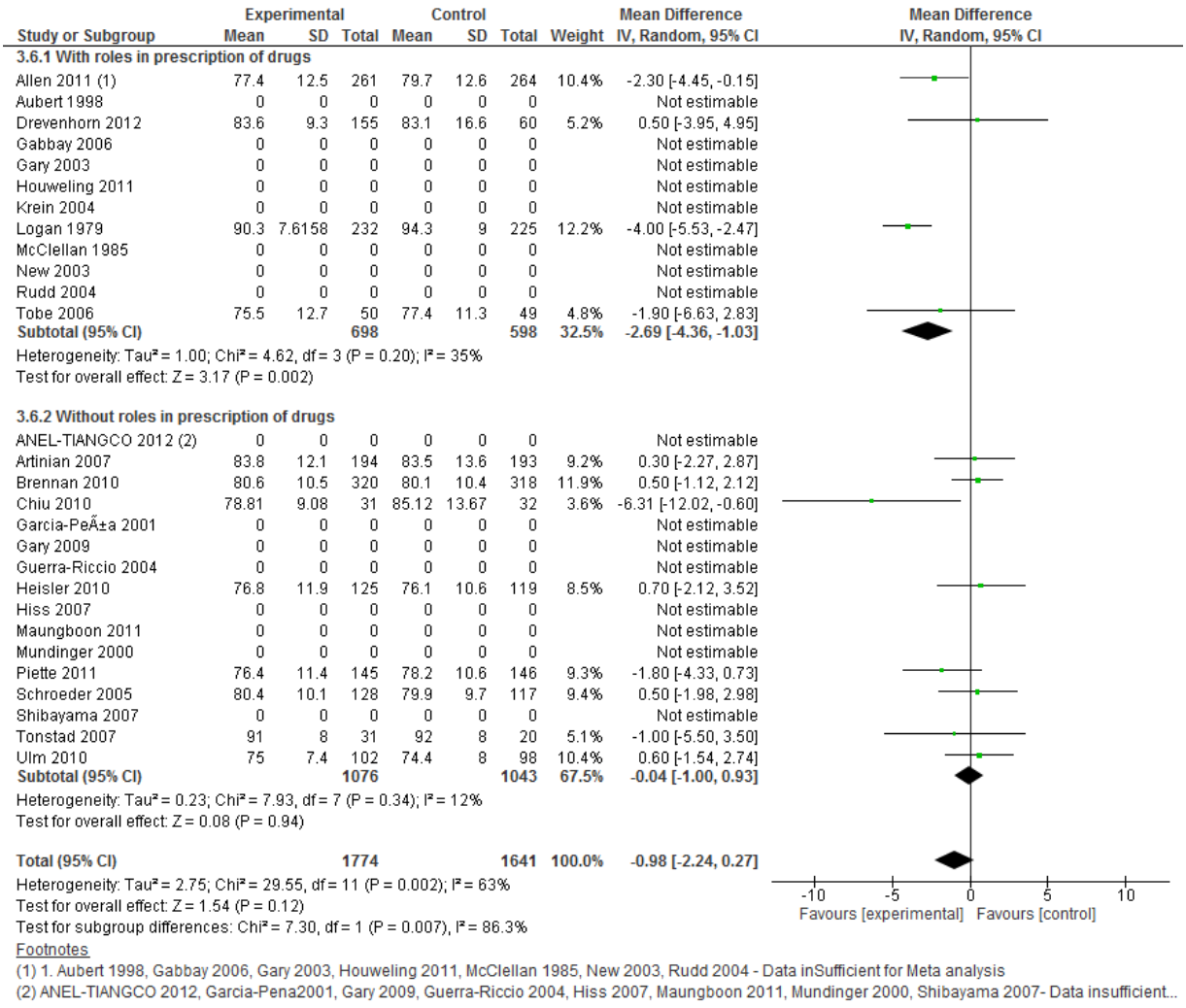


Footnotes

(1) 1. Aubert 1998, Gary 2003, Houweling 2011, McClellan 1985, New 2003- Data insufficient for meta-analysis

(2) Anel-Tiangco 2012, Garcia-Pena 2001, Gary 2009, Maungboon 2011, Mundinger 2000, Schroeder 2005 - Data insufficient for meta-analysis

Figure 3.6: Effect of nurse-delivered interventions on end point diastolic blood pressure with and without roles for nurses in prescription of drugs.



Footnotes

(1) 1. Aubert 1998, Gabbay 2006, Gary 2003, Houweling 2011, McClellan 1985, New 2003, Rudd 2004 - Data inSufficient for Meta analysis

(2) ANEL-TIANGCO 2012, Garcia-Pena2001, Gary 2009, Guerra-Riccio 2004, Hiss 2007, Maungboon 2011, Mundinger 2000, Shibayama 2007- Data insufficient...

Effect on achievement of control of blood pressure

Fifteen trials [82, 83, 99, 100, 102–104, 110, 111, 113, 114, 116–118, 121] reported the effects of nurse-delivered interventions on blood pressure control or achieving target blood pressure. Analyses were available for 4953 subjects (2275 in EG, 2156 in CG and 522 in three trials that did not report group wise participants) from the randomised 5375 participants (2642 in EG, 2521 in CG and 522 in three studies that did not report group-wise participants). See Table 3.5.

The target blood pressure was 140/90 mm Hg in studies exclusively on hypertension and 130/80 mm Hg in participants with Type 2 Diabetes Mellitus. In one of the studies, the target blood pressure was set at 120/80 mm Hg [111] while two studies had a target of <90 mm Hg diastolic blood pressure [102, 103]. Eight studies reported no difference between groups while the remaining seven studies reported significant effects in favour of the intervention. The mean Jadad score for all 15 studies was 2.93. The studies that reported favourable effect had a mean score of 3.14 while the others studies had a mean score of 2.6.

Of the seven trials which studied nurse-delivered interventions, blood pressure control improved significantly (mean difference range 16% to 30%) in only four trials [82, 83, 104, 116] (mean Jadad score: 3.25). Similarly, of the eight trials [99, 102, 103, 113, 114, 117, 118, 121] (mean Jadad score: 2.5) in which nurse-delivered interventions with drug prescriptions were attempted, favourable effects (mean difference range: 21% to 35%) were reported from only three studies [102, 117, 118] (mean Jadad score: 3). Due to high heterogeneity of studies, meta-analysis was not attempted.

Effect on glycaeted /glycosylated haemoglobin (HbA1c) level

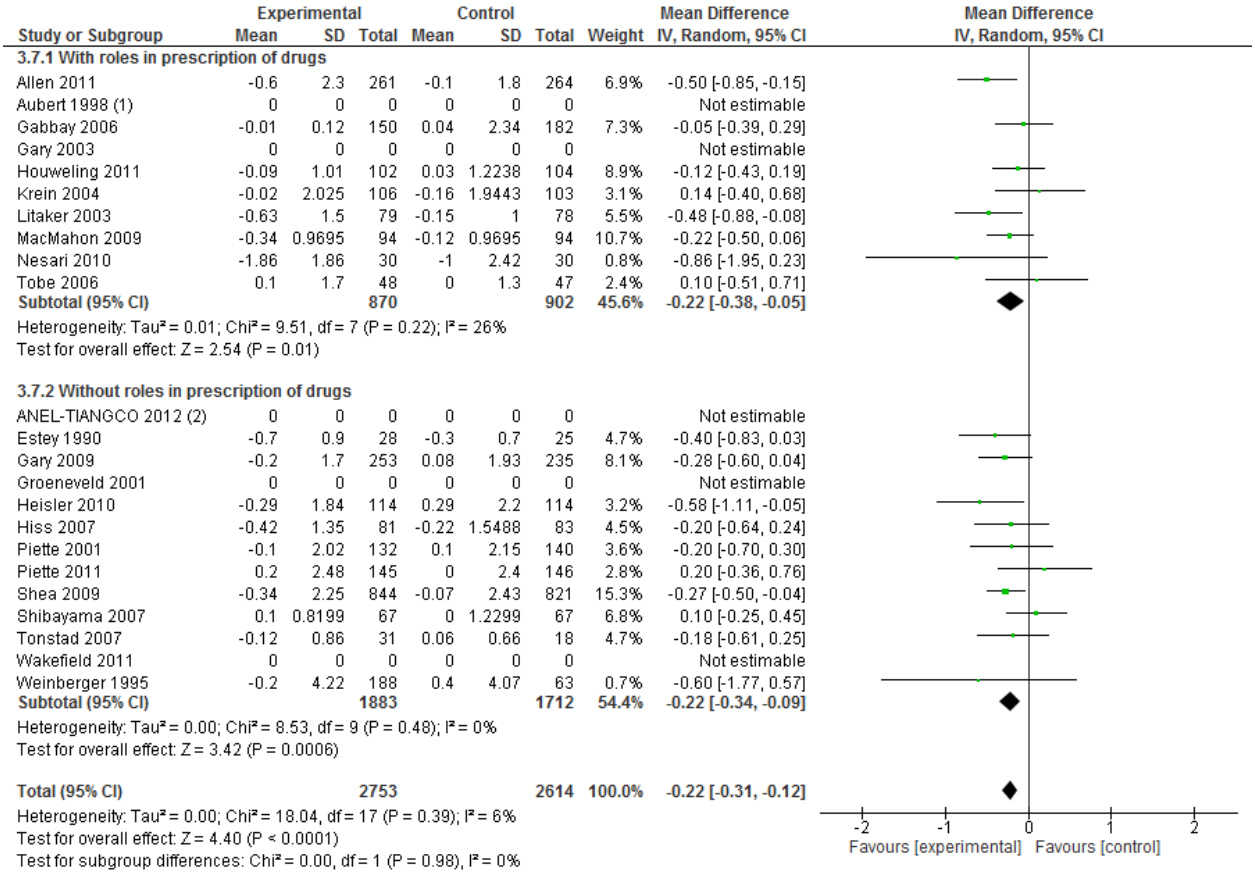
Effect of nurse-delivered interventions on mean HbA1c level was reported in 23 trials. A total of 7060 participants (3461 in EG, 3353 in CG and 246 in two studies that did not report group wise participants) was randomised and data from 6707 participants (3397 in EG and 3310 in CG) were analysed. Eight studies (1755 in EG, 1507 in CG, and analysis available for 3175 participants) reported favourable effect on mean HbA1c level. Fourteen trials which had a total of 3551 participants (1676 in EG, 1815 in CG, and analysis available for 3272 participants) could not find any effect of the interventions. Mean Jadad scores for all the studies, studies reporting favourable effects, studies reporting no difference and the studies with comparator group showing positive effects, were 2.72, 3.18, 2.36 and 3, respectively (Table 3.6).

Nurse-delivered interventions with roles in prescriptions reported significant reduction of HbA1c level, with the mean reduction ranging from -0.22 to -1.4% in six trials [84, 87, 91, 117, 121, 122] (mean Jadad score: 3.17), while four studies [92–94, 99] (mean Jadad score: 2.7) reported no significant changes. Interventions without roles for nurses in prescribing medicines reported significant mean reduction in HbA1c level (range: -0.29 to -0.4%) in only three [86, 97, 119] (mean Jadad score: 3.2) out of 13 trials [85, 86, 89, 90, 94–98, 100, 101, 109, 119] (mean Jadad score: 2.86).

Meta-analysis of the above trials showed that nurse-delivered interventions resulted in a mean reduction of 0.22% in HbA1c levels (CI: 0.12 - 0.31%; I^2: 6%; random effects; 18 studies). Interventions with (-0.22%; CI: 0.05-0.38%; I^2: 26%; eight studies; random effects) and without roles for nurses in drug prescription (-0.22%; CI: 0.09 - 0.34%; I^2=06%; 10 studies, random effects) had similar results. Results from pooled analysis were

also similar in the fixed effects model. In trials with prescription roles for nurses, eight studies (mean Jadad score: 2.75) reported sufficient data for including in meta-analysis whereas two studies (mean Jadad score: 2.5) were excluded due to insufficient data in their reports. Similarly, for trials without roles for nurses in prescription, meta-analysis was limited to ten studies (mean Jadad score: 2.9) and three studies (mean Jadad score: 1.7) were excluded due to insufficient data. See Figure 3.7 for details.

Figure 3.7: Effect of nurse-delivered interventions on HbA1c levels in trials with and without roles for nurses in prescription of drugs



Footnotes

(1) Aubert 1998, Gary 2003, Gary 2003 Data Insufficient for Meta-analysis

(2) 2. ANEL-TIANGCO 2012, Grenveld 2001, wakefield 2011- Data insufficient for Meta-analysis.

Effect on glycaemic control / target achievement

Glycaemic control as an outcome was reported in six studies [86, 88, 99, 100, 117, 118]. Various glycaemic control targets (in HbA1c%) set by the trials were <6.5% (two trials), <7.0% and <8.5% (one trial), <7.2% (one trial) and <8% (two trials). A total of 1832 participants were randomised in these groups of studies and analysis was available for 1323 participants. Three studies found no difference between the study groups, whereas the remaining three studies reported favourable effect on glycaemic control. In these three studies, one study [118] reported results from 139 participants only (those with HbA1c >9.0% of the total 556 participants randomised). The mean Jadad score for the entire group of studies was 2.5 and that of studies reporting favourable effect and no effect was 3 and 2, respectively (Table 3.7).

Three trials each were in the groups with and without roles for nurses in drug prescription. In the former group [99, 117, 118] (mean Jadad score: 2.33), two trials (mean Jadad score: 3) reported beneficial effects as compared to only one (Jadad score: 3) in the latter [86, 88, 100] (mean Jadad score: 2.67). Due to high heterogeneity of studies, meta-analysis was not attempted.

3.1.5 Discussion

This systematic review found that nurse-delivered interventions were predominantly carried out in high-income countries to evaluate their effect on health outcomes in people with hypertension and/or diabetes. These trials attempted multiple roles for nurses in the interventions at primary care level. Only half of the 32 trials and 10 out of 28 trials could demonstrate favourable effect on SBP and DBP, respectively. Pooled estimates of

interventions showed significant lower SBP, ranging from -3.37 to - 4.81 mmHg in the intervention arm, with higher reduction in trials with drug prescription roles for nurses. The degree of reduction was lower in DBP, as it ranged between -1.93 to -3.51 mmHg, with greater reduction in trials with drug prescription roles for nurses. However, nurse-delivered interventions, on pooled analysis, demonstrated similar effect on reduction in mean HbA1c level (-0.22%) in trials with and without roles for nurses in drug prescription.

The studies included in this review were characterised by wide heterogeneity. While some of the studies used a treatment algorithm for the use of nurses in prescribing medications, some studies restricted the roles of nurses to patient education or patient assessment and, therefore, it was not possible within this review to segregate the components of each intervention and judge their individual effect. However, the pooled estimates of the trials showed that the extent of reduction in blood pressure or HbA1c level observed was similar to those in drug trials. For example, the Blood Pressure Lowering Treatment Trialists' Collaboration demonstrated that the reduction in blood pressure with the use of ACE-Inhibitors was to the tune of -4.6 mmHg and -2.1 mmHg, for SBP and DBP [123], respectively. A reduction of 10 mmHg of systolic blood pressure can lead to 20-25% reduction in major cardiovascular events [124]. Moreover, the magnitude of the blood pressure reduction is an important predictor of cardiovascular benefits obtained and is independent of the choice of drug [123]. Similarly, in people with diabetes, the ACCORD, ADVANCE, and VADT trials have demonstrated that cardiovascular risk factor control, along with glucose monitoring, is important to control the onset of complications. Therefore, these findings suggest a potential role of nurse-delivered interventions at primary care level for hypertension and diabetes management, even in low resource settings

and even with the use of simple medications and therapeutic lifestyle modifications for patients. Another important finding is that the magnitude of the effect on health outcomes was not greatly different between trials with and without roles for nurses in drug prescription. This finding has implications in many countries, including India, where nurses are not legally permitted to prescribe medicines. Trained nurses under the supervision of a physician could deliver hypertension and diabetes care with greater roles for them in patient assessment, patient education, lifestyle counselling, follow-up and facilitation of compliance/adherence to medications etc., which were among the identified roles played by nurses in the interventions reviewed.

A recent systematic review of interventions for hypertension at primary care level has found that an organised system of regular review, along with vigorous antihypertensive drug therapy, to be important part of successful interventions [125]. In countries like India, where the workload of physicians at primary care level is very high, an additional workforce, such as nurses, will support and strengthen primary healthcare. Another systematic review by Martınez-Gonzalez, et al, which assessed the impact of physician-nurse substitution in primary care on several clinical conditions, including hypertension and diabetes, reported a significant SBP-reducing effect of nurse-delivered interventions compared to physician care [126]. With respect to DBP and HbA1c levels, nurse-led interventions were on a par with physicians [126].Although largely from developed world, such evidence also points to the important role of nurses in hypertension and diabetes care in settings where access to the services of physicians is limited.

Limitations of the review

This review had a broad inclusion criterion and among 41 studies included, nurse-delivered care was studied as an independent intervention in only seven studies, while other studies had several additional components, such as technology, involvement of other healthcare workers as part of the intervention. Hence, the effect size observed in the pooled analysis need to be interpreted with caution as it does not provide an estimate on the role of nurses in care alone. Further, since blood pressure and HbA1c levels were reported, either as final blood pressure or change from baseline, less pooling of results was possible. Hence a sizable number of trials did not report sufficient data to be included in the meta-analysis carried out for various outcomes. Methodological quality of excluded trial groups were not much different from those included. Had such studies also been in the meta-analysis, the pooled results could vary either way. Another limitation of this review is the inclusion of all studies, irrespective of their primary or secondary outcomes, which ended up in including studies with smaller sample size too.

Due to heterogeneity of the studies included, the control groups differed considerably across the included studies. In 10 studies, the control group received stepped-up care, which could have lowered the effect level of nurse-delivered interventions. Further, all the studies had randomisation at patient level. Hence, there were chances that well-trained, experienced and highly motivated nurses delivered the interventions and there was possible contamination with the control arm, which has a bearing on outcomes.

In most studies included in this review, the duration of follow-up was relatively short. Only seven studies followed participants with hypertension for more than 12 months, while only

six studies followed-up participants with diabetes for more than 12 months. Further, there were difference in methods used for assessing the outcome, such as blood pressure (sphygmomanometer / electronic BP monitors /24-hour ambulatory blood pressure monitoring), in addition to differences in target level of blood pressure / HbA1c in patients under treatment.

The mean Jadad scores of studies in this review ranged from 2.5 to 2.93 on a scale of 1-5. Fourteen studies did not report the method used for randomisation. Since double blinding was not possible in nurse-delivered care, alternative options, such as blinding the outcomes, blinding the observer and blinding the statisticians, could have reduced the bias. However, 20 studies did not report blinding of either the observer or the statisticians. Nineteen studies did not provide any data on loss to follow-up or had more than 10% of patients lost to follow-up. Hence, there is a need for more studies with sound methodology for assessing similar and well-defined outcomes. Further, the studies were from developed nations, which differ substantially from the health systems of the developing world. Hence, far more good quality trials in larger numbers of patients are required to generate conclusive evidence, particularly for developing countries. Another weakness of this review was that no search for grey literature was attempted and studies published in non-English languages were excluded. Furthermore, the authors of studies were not contacted to further obtain or clarify missing information.

3.1.6 Conclusion

Nurse-delivered interventions appear to be an important strategy for the management of hypertension and Type 2 Diabetes Mellitus in primary care settings. However, more

evidence is required from developing countries to recommend this strategy as part of primary care services.

3.1.7 Search strategy

PubMed

The following search strategy was employed to search the MEDLINE database and the filters Randomized controlled trials were applied.

"Nurses"[Mesh] OR "nurse practitioners"[MeSH Terms] OR "nurse clinicians"[MeSH Terms] OR "Nursing Care"[Mesh] OR "Nursing"[Mesh] OR "nursing" [Subheading] OR "Primary Nursing"[Mesh] OR "Nursing"[Mesh] OR "Evidence-Based Nursing"[Mesh] OR "education, nursing, continuing"[MeSH Terms] OR nurse[Title word] OR nursing[Title word] OR(("education, medical, continuing"[MeSH Terms] OR "Practice Guidelines as Topic"[Mesh] OR "Health Planning Guidelines"[Mesh] OR "Guideline"[Publication Type] OR "standards"[Subheading] OR "Standard of Care"[Mesh] OR "Guideline Adherence"[Mesh] OR "Health Systems Plans"[Mesh] OR "Clinical Protocols"[Mesh] OR "Nutrition Policy"[Mesh] OR "Patient Care Planning"[Mesh] OR "Provider feedback"[All Fields] OR "Patient Care"[Mesh] OR "Patient Care Team"[Mesh] OR "Progressive Patient Care"[Mesh] OR "Patient Care Planning"[Mesh] OR "Patient Care Management"[Mesh] OR "Continuity of Patient Care"[Mesh] OR "Episode of Care"[Mesh] OR "Disease Management"[Mesh] OR "Evidence-Based Emergency Medicine"[Mesh] OR "Evidence-Based Practice"[Mesh] OR "Evidence-Based Medicine"[Mesh] OR "Ambulatory Care"[Mesh]) AND nurse[Text Word]) AND (Diabetes mellitus, Type 2[Mesh] OR Hypertension[MeSH])

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'nurse'/exp OR 'nurse practitioner'/exp OR 'nursing'/exp OR 'nursing care'/exp OR 'nursing education'/exp OR ('practice guideline'/exp AND nurse) OR ('health care planning'/exp AND nurse) OR ('health care quality'/exp AND nurse) OR ('patient care planning'/exp AND nurse) OR ('primary health care'/exp AND nurse) OR 'primary nursing'/exp OR ('patient care'/exp AND nurse) OR 'nursing home patient'/exp OR ('disease management'/exp AND nurse) OR 'evidence based nursing'/exp OR ('ambulatory care'/exp AND nurse) AND ('non insulin dependent diabetes mellitus'/exp OR 'hypertension'/exp) AND ('clinical trial'/de OR 'controlled study'/de OR 'human'/de OR 'practice guideline'/de OR 'randomized controlled trial'/de) AND [embase]/lim

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Table 3.1 Characteristics of the included studies

First author, Year	Country	Condition	Patients									Intervention		
			Sample Size			Age(Mean(SD))/range			% of males			Treatment		Duration of study (in months)
			EG	CG	Total	EG	CG	Overall	EG	CG	Over all	Experimental Group (EG)	Control Group (CG)	
Logan, 1979 [102]	Canada	HTN	232	225	457	46.8±0.6	46.3±0.7		80.6	76.9		NU delivered care at Work site	Usual care	6 months
McClellan, 1985[103]	USA	HTN	50	53	103	52.1	53.7		43.4	32.0	39	NU case management	Usual care	12 months
Estey AL, 1990[85]	Canada	DM			60	56.2±11.1	54.2±13.3		54	39		Tele-monitoring and house visit by NU and SMBG with 3 day training program on DM skills	3 day training program on DM skills	4 months
Weinberger, 1995[86]	USA	DM	204	71	275	63.9±8.6	63.2±8.3		98.5	100		Tele-monitoring and patient education by NU	Usual care	12 months
Aubert RE, 1998[87]	USA	DM	71	67	138	53	54		37	43		NU treating based on algorithm and Diabetes education program	Diabetes education program	12 months
Mundinger MO, 2000[120]	USA	DM/ HTN	474 (1181)	367 (800)	841							NU led care	Usual Care	6 months
Piette JD, 2000[88]	USA	DM	137	143	280	56±10	53±10		39	44	41	Tele-monitoring by NU and automated tele-education	Usual care	12 months
Garcia-pena C, 2001[104]	Mexico	HTN	364	354	718	70.8±6.92	70.6±7.11		35	37.1		NU home visit for patient education and review of pharmacological treatment	Usual care	6 months
Groeneveld Y, 2001[89]	Netherlands	DM	133	155	288	62.7±11	62.3±10		34	46.4	41.9	Patient education and review by NU and Dietician advice	Usual care	12 months

First author, Year	Country	Condition	Patients									Intervention		
			Sample Size			Age(Mean(SD))/range			% of males			Treatment		Duration of study (in months)
			EG	CG	Total	EG	CG	Overall	EG	CG	Overall	Experimental Group (EG)	Control Group (CG)	
Piette JD, 2001[90]	USA	DM	146	146	292	60±10	61±10		95	99	97	Tele-monitoring by NU and automated tele-education	Usual care	12 months
Gary TL, 2003[91]	USA	DM	38, 36	41, 34	186	59±11 60±7	59±9 57±8	59±9	24 22	22 26	76.5	1. Nurse-delivered care 2. Nurse-delivered care and CHW facilitated preventive care	3. CHW facilitated preventive care 4. Usual care	24 months
Litaker D, 2003[121]	USA	DM/ HTN	79	78	157	60.5±8.5	60.6±9.6		41	42	41.4	NU treating the patients based on algorithm and suggestions by physician	Usual care	16 months
New JP, 2003[114]	UK	DM+ HTN	506	508	1014	63.5	63.7		51	49		NU led hypertension care	Usual care	12 months
Guerra Riccio, 2004[105]	Brazil	HTN	48	52	100	54±10	53±9		46	60.8	53	Frequent (12 visits) Nurse visits to improve medication adherence	2 Nurse visits to improve medication adherence	6 months
Krein SL, 2004[92]	USA	DM	123 (106)	123 (103)	246	61±10	61±11		98	95	96.7	Nurse provided adherence support	Usual care	18 months
Rudd P, 2004[106]	USA	HTN	74	76	150	59±10	60±9		50	44		Tele mediated Nurse led care including drug changes and with permission to initiate a new drug	Usual care	6 months
Schroeder K, 2005[107]	UK	HTN	128	117	245	67.9±10.3	68.2±9.4		56	54		Nurse led adherence support + electronic medication monitor	Electronic medication monitoring + usual care	6 months
Gabbay RA, 2006[93]	USA	DM	150	182	332	64±20	65±12		52	57	54%	Nurse delivered care including drug prescription under the	Usual care	12 months

First author, Year	Country	Condition	Patients									Intervention		
			Sample Size			Age(Mean(SD))/range			% of males			Treatment		Duration of study (in months)
			EG	CG	Total	EG	CG	Overall	EG	CG	Overall	Experimental Group (EG)	Control Group (CG)	
												guidance of PCP		
Tobe SW, 2006[115]	Canada	DM+ HTN	50	49	99	55.4±12.9	55.9±11.5		38	39	38.5	Algorithm based nurse led care under the indirect supervision specialist	Usual care	12 months
Artinian NT, 2007[108]	USA	HTN	194	193	387	59.1±13.0	60.2±12.3		41.2	30.1	35.6	Tele counselling by NU and Tele-monitoring of BP	Enhanced usual care	12 months
Hiss RG, 2007[94]	USA	DM	95	102	197	55.7±13.1	57.0±11.4		36	32	33.3	Individualized care and patient education NU	Baseline evaluation sent to PCP	6 months
Shibayama T, 2007[95]	Japan	DM	67	67	134	61±8	62±7		65.2	65.2	65.2	Lifestyle counselling by NU	Usual care	12 months
Tonstad S, 2007[109]	Norway	HTN	31	20	51	55±9	55±8		67.7	83.3		Lifestyle counselling by NU	Usual care	6 months
Mc Lean DL, 2008[116]	Canada	DM+ HTN	115	112	227	63.7± 12.7	66.2±11.3	64.9±12.1	54.5	65.2	59.9	PH&NU- CVD risk reduction and hypertension education + referral	Pamphlet on diabetes and diabetes advice	6 (24 weeks)
Bosworth HB, 2009[110]	USA	HTN	150 144	151 143	588	62±11 65±11	63±11 64±12	63±11	97 99	97 99	98	DSS + Tele-behavioural intervention by NU; Tele-behavioural intervention by NU	DSS; Patient reminder control	24 months
Gary TL, 2009[96]	USA	DM	269	273	542	59±11	56±11		27	26	26.5	NCM clinic visits (>1) and CHW home visits(1-3 times yearly)	Tele follow up for preventive screenings yearly (1-2) and informational mailings	24 months
MacMohan Tone J, 2009[117]	Ireland	DM+ HC / HTN	200	101	99	61.7±8.8	61.6±8.8		53.2	55.3	54.2	NU – Treating and educating patients	General diabetes advise	12 months
Shea S,	USA	DM	844	821	1665	70.8±6.5	70.9±6.8		36.5	37.9	37.2	NU care +	Usual care	60 months

First author, Year	Country	Condition	Patients									Intervention		
			Sample Size			Age(Mean(SD))/range			% of males			Treatment		Duration of study (in months)
			EG	CG	Total	EG	CG	Overall	EG	CG	Overall	Experimental Group (EG)	Control Group (CG)	
2009[97]												Telemedicine (Web based)		
Brennan T, 2010[111]	USA	HTN	320	318	638	55.3±11.5	56.1±11.5		35.6	30.5	33.1	Disease management program including care calls by NU	Light support educational program	12 months
Chiu CW, 2010[82]	China	HTN	31	32	63	53.3±7.82	54.4±7.57	53.87±7.6	22.6	43.8	33.3	NU care for healthy behaviours + nurse tele follow up	Nurse care	2 months
Heisler M, 2010[98]	USA	DM	119	125	244	62.3±6.6	61.8±6.1	62.0±6.3	100	100	100	NU care management	Reciprocal peer support	6 months
Nesari M, 2010[84]	Iran	DM	30	31	61	51.9±7.6	51±8.2		36.7	20	28.3	Tele follow up by NU	Usual care	3 months
Ulm K, 2010[112]	Germany	HTN	102	98	200	65.8±8.9	65.1±8.5		59	48	53.5	Individualized lifestyle education for patients by NU	Usual care	2 months
Allen JK, 2011[122]	USA	DM/ HTN/ CVD	261	264	525	54.3±12.0	54.7±11.5		28.3	29.2	29.6	NU/ CHW treating and educating based on protocol	Enhanced usual care	12 months
Houweling, 2011[99]	Netherlands	DM	102	104	206	69.5±10.6	67.1±11.0		52.9	42.3	47.5	NU delivered care based on protocol	Standard care	12 months
Ishani, 2011[118]	USA	DM + HTN/ HC	278	278	556	64.9±8.9	65.8±9.1		99.6	97.5	98.6	NU case management based on protocol	Usual care	12 months
Maungboon P, 2011[83]	Thailand	HTN			211			59.1±9.3			62.2	NU-PH model care based on protocol	Usual care	
Piette JD, 2011[100]	USA	DM	145	146	291	55.1±9.4	56.0±10.9	56.0±10.1	49	50	49.5	NU administered CBT + walking	Enhanced Usual care	12 months
Wakefield, 2011[119]	USA	DM + HTN	93 102	107	302	67.8±10 68.4±9.5	67.9±9.9		99 99	96	98	High intensity protocol based NU care Low intensity NU care	Usual care	6 (follow up at 12 months)

First author, Year	Country	Condition	Patients									Intervention		
			Sample Size			Age(Mean(SD))/range			% of males			Treatment		Duration of study (in months)
			EG	CG	Total	EG	CG	Overall	EG	CG	Overall	Experimental Group (EG)	Control Group (CG)	
Anel-Tiangco, 2012[101]	USA	DM	313	232	545							NU case management and MI	Usual care	24 months
Drevenhorn E, 2012[113]	Sweden	HTN	137	51	188							NU trained in SOC, MI and protocol provided care	Usual care	24 months

BP: Blood Pressure; CBT: Cognitive Behavioural Therapy; CG: Control Group; CHW: Community Health Worker; CVD: Cardiovascular diseases; DM: Type 2 Diabetes Mellitus; DSS: Decision Support System; EG: Experimental Group; HC: Hypercholesterolemia; HTN: Hypertension; MI: Motivational Interview; NCM: Nurse Case Manager; NU: Nurse; PCP: Primary care physician; PH: Pharmacist; SD: Standard Deviation; SMBG: Self-Monitoring of Blood Glucose; and SOC: Stages of Change.

Table 3.2: Nurse-delivered interventions - Individual components and models studied

First author, Year	Individual Components of Intervention	Nurse care models	Nurse care classification for this review
Logan, 1979 [102]	PR, PE, TA, DP, PI, RE, MR, PRR, WS	PA + MP + PM	NU + MP
McClellan, 1985[103]	PE, PRR, PR, TA, DP, FU, FC, PED, RI	PA + MP + PM + PAED	NU + MP
Estey AL, 1990[85]	TM, PED, RI, FU, FC, RE,	PA + PM + PAED	NU
Weinberger, 1995[86]	PED, FC, PE, PI, FU, RE	PA + PM + PAED	NU
Aubert RE, 1998[87]	PR, DP, LC, FU, PRR	PA + MP + PM + PAED	NU + MP
Mundinger MO, 2000[120]	PE, DP, RE, MR, PRR	PA + MP + PM + PAED	NU + MP
Piette JD, 2000[88]	AT, TM, RE	PM	NU
Garcia-pena C, 2001[104]	HV, PE, PRR, LC, TA, MR, FC,	PA + PM + PAED	NU
Groeneveld Y, 2001[89]	LC, PRR, RE, FU	PA + PM + PAED	NU
Piette JD, 2001[90]	AT, TM, RE, MR	PA + PM	NU
Gary TL, 2003[91]	PE, TM, PED, LC, FU, RE, DP	PA + PM + PAED + MP	NU +MP
Litaker D, 2003[121]	PR, PED, FU, RI, LC, TM, DP	PA + PM + PAED + MP	NU + MP
New JP, 2003[114]	PRR, MR, PE, TA, PED, LC, FU, RI, DP	PA + PM + PAED + MP	NU + MP
Guerra Riccio, 2004[105]	PE, MR, RI, FC, FU	PA + PM + PAED	NU
Krein SL, 2004[92]	ABPM, PED, RI, FU, PE, MR, PR, RE, LC, TM, DP	PA + PM + PAED + MP	NU + MP
Rudd P, 2004[106]	ABPM, LC, FC, TM, DP, PR, TA, RE	PA + PM + PAED + MP	NU + MP
Schroeder K, 2005[107]	FC, RI, FU, PED, TA	PA + PM + PAED	NU
Gabbay RA, 2006[93]	PR, PE, FU, TA, PED, TM, RE, MR, DP	PA + PM + PAED + MP	NU + MP
Tobe SW, 2006[115]	PR, DP, MR, FU, RE	PA + PM + MP	NU + MP

First author, Year	Individual Components of Intervention	Nurse care models	Nurse care classification for this review
Artinian NT, 2007[108]	TM, TA, LC, FC, RI, PRR	PA + PM + PAED	NU
Hiss RG, 2007[94]	LC, PI, TA, PRR, RE, FU	PA + PM + PAED	NU
Shibayama T, 2007[95]	LC, PE, TA, FU, FC, PI	PA + PM + PAED	NU
Tonstad S, 2007[109]	PE, LC, RI	PA + PM + PAED	NU
McLean DL, 2008[116]	LC, PE, RE, FU	PA + PM + PAED	NU
Bosworth HB, 2009[110]	CDSS, TM, PED, FC, FU, LC	PA + PM + PAED	NU
Gary TL, 2009[96]	PE, TM, PED, LC, FU, RE, TA	PA + PM + PAED	NU
MAcMohan Tone J [117]	LC, RI, TA, DP, RE	PA + PM + PAED + MP	NU + MP
Shea S, 2009[97]	ABPM, ABGM, PE, TA, RE, PAED	PA + PM + PAED	NU
Brennan T, 2010[111]	PED, TN, RE, LC, PE, TA	PA + PM + PAED	NU
Chiu CW, 2010[82]	TM, PR, PE, MR, LC, FC	PA + PM + PAED	NU
Heisler M, 2010[98]	MR, PRR, TM, PED	PA + PM + PAED	NU
Nesari M, 2010[84]	PED, LC, TM, RI, PI, DP	PA + PM + PAED + MP	NU + MP
Ulm K, 2010[112]	LC, PED, PE, FU	PA + PM + PAED	NU
Allen JK, 2011[122]	LC, DP, TA, PR, FC, FU	PA + PM + PAED +MP	NU + MP
Houweling, 2011[99]	PR, DP	PA + MP + PAED	NU + MP
Ishani, 2011[118]	LC, TA, PRR, PR, TM, RE, DP	PA + PM + PAED + MP	NU + MP
Maungboon P, 2011[83]	PED, FU, PRR	PA + PM + PAED	NU
Piette JD, 2011[100]	LC, FU, RE	PM + PAED	NU
Wakefield, 2011[119]	PR, CDSS, PED, FC, PRR, TM	PA + PM + PAED	NU
Anel-Tiangco, 2012[101]	PED, LC, MI	PM + PAED	NU
Drevenhorn E, 2012[113]	PED, LC, DP	PAED + MP	NU + MP

Second Column:- ABGM: Automated Blood Glucose Monitoring; ABPM: Automated Blood Pressure Monitoring; AT: Automated Telephone calls consisting a hierarchically structured recorded human voice queries which performed periodical patient assessment and provision of health tips, positive reinforcement, identification of problems and periodical reporting to the nurses); CDSS: Computerized Decision Support System; DP: Drug Prescription; FC: Facilitate Compliance / adherence to medication; FU: Follow-up; HV: Home Visits; LC: Lifestyle Counselling (dietary modifications, physical activity promotion, tobacco cessation and limiting alcohol usage); MI: Motivational Interviewing. PED: Patient Education; PE: Patient Examination, history taking, general physical examination, collection of blood and urine samples; PI: Problem Identification; PR: Protocol; PRR: Patient's Record Review; RE: Referral; MR: Medication Review; RI: Reinforcement; TA-Target Approach; TM: Tele-monitoring/follow-up by nurses; and WC: Wallet Card.

Third Column: PA: Patient assessment (PE+ /MR+/ PRR +/ WC); PAED: Patient education (PED +/LC+/MI); PM: Patient management (TA +/ PI+/ FC+/TM+/FU+/RE +/HV); and MP: Guidelines based Medication Prescription (PR+/DP).

Fourth Column: MP: Medication Prescription; and NU: Nurse.

Table 3.3: Effects of nurse-delivered interventions on systolic blood pressure

Author, year	Condition	N Recruited (EG, CG)	N Analysed (EG, CG)	Follow up, mean/range of duration(in months)	Intervention	Mean Systolic blood pressure (±SD)				Mean difference (SE / 95% confidence interval)	Jadad score
						Experimental Group		Control Group			
						Before	After	Before	After		
McClellan, 1985 [103]	HTN	50, 53	25, 14	12 months	NU + DP	158.4	140.8	168.5	137.6	NS	2
Aubert RE, 1998 [87]	DM	71, 67	100	12 months	NU + DP					SBP increased EG vs. CG 1.9 vs. 6.1 mmHg, p>0.2.	2
Mundinger MO, 2000 [120]	DM/HTN	354, 273	211, 145	6 months	NU + DP		137		139	NS, p=0.28	2
Garcia-Pena C, 2001 [104]	HTN	364, 354	364, 354	6 months	NU	162.1±18.4		161.9±18.4		MD: -3.11 mmHg, p=0.03	4
Gary TL, 2003 [91]	DM	186	(38, 36), (41, 34)	24 months	NU + DP	125 ±15 129 ±14		129 ±20 127 ±20		No difference	3
New JP, 2003 [114]	DM+HTN	506, 508	506, 508	12 months	NU + DP	159	147	159	149	-1.95 mmHg (-4.45 to 0.60), p=0.13	4
Guerra-Riccio, 2004 [105]	HTN	48,52	48, 52	6 months	NU					36±6 vs. 17±4 mm Hg, p<0.05	2
Krein SL, 2004 [92]	DM	123, 123	106, 103	18 months	NU + DP	145 ±21	146 (142 to 151)	145 ±20	144 (140 to 149)	p=0.53	3
Rudd P, 2004 [106]	HTN	74, 76	69, 63	6 months	NU + DP					14.2±18.1 vs. 5.7±18.7 mmHg (p<0.01)	3
Schroeder K, 2005 [107]	HTN	128, 117	200	6 months	NU	149±15.2 (n=127)	142.9±17.6	152.1±17.5 (n=114)	147.7±20.9	-2.7 mmHg (-7.2 to 1.8)	2
Gabbay RA, 2006 [93]	DM	150, 182	150, 182	12 months	NU + DP	137±19	136±17	129±18	138±19	p<0.001	1
Tobe SW, 2006[115]	DM+HTN	50, 49	48, 47	12 months	NU + DP	149.7±10.5	125.7±16.6	150.5±19.1	133.5±18.1	–24.0±13.5 vs. –17.0±18.6 mmHg, p>0.05	3

Author, year	Condition	N Recruited (EG, CG)	N Analysed (EG, CG)	Follow up, mean/range of duration(in months)	Intervention	Mean Systolic blood pressure (±SD)				Mean difference (SE / 95% confidence interval)	Jadad score
						Experimental Group		Control Group			
						Before	After	Before	After		
Artinian NT, 2007 [108]	HTN	194, 193	194,193	12 months	NU	156.8±19.6	145.0±21.0	155.9±19.2	148.1±22.3	-13.0 vs. -7.0 mmHg, p=0.04	4
Hiss RG, 2007 [94]	DM	95, 102	81, 83	6 months	NU	136±2.5		129±2.1		–7.3±2.4 vs. 4.1±2.2 mmHg, p=0.007	1
Shibayama T, 2007 [95]	DM	67, 67	66,65	12 months	NU	135±16		132±15		2 mmHg (-3 to 6) vs. 2 mmHg (-2 to 5), p=0.43	3
Tonstad S, 2007 [109]	HTN	31, 20	29, 16	6 months	NU	157±9	147±9	153±9	143±10	No difference	3
Mc Lean DL, 2008 [116]	DM+HTN	115, 112	115, 112	6 months (24 weeks)	NU	NR	NR	NR	NR	5.6 (2.1) mmHg, p=0.008	4
Bosworth HB, 2009 [110]	HTN	(150,144), (151,143)	(150,144), (151,143)	24 months	NU	139.2±1.4 138.8±1.4	139.1±1.4 141.6±1.4	136.8±1.7 136.3±1.6	136.9±1.6 136.8±1.6	No difference	4
Gary TL, 2009[96]	DM	269, 273	253, 235	24 months	NU	137±21		137±20		No difference	4
MacMohan Tone J, 2009 [117]	DM + HTN/HC	101, 99	94,94	12 months	NU + DP	149.4 ± 21.9		146.9 ± 20.9		10.5 ± 1.8 vs. 1.7 ± 2.0 mmHg, p=0.001	3
Shea S, 2009 [97]	DM	844, 821	844, 821	60 months	NU	140.34±0.73 (SE)	135.83±0.87 (SE)	141.85±0.74 (SE)	140.15±0.86 (SE)	4.32 mmHg (1.93, 6.72)	4
Brennan T, 2010 [111]	HTN	320, 318	320, 318	12 months	NU	133.2±17.9	126.8 ±16.9	132.9±20.5	129.5±18.2	123.6 vs. 126.7 mmHg, p=0.03	3
Chiu CW, 2010 [82]	HTN	31, 32	31, 32	2 months	NU	147.19±18.95	128.16±15.66	148.5±17.93	140.53±16.59	4.25 vs. 20.50 mmHg, p<0.003	4
Heisler M, 2010 [98]	DM	119, 125	103, 113	6 months	NU	136.4±16.9	135.0±17.7	140.3±18.6	136.9±16.8	-3.4 vs. -1.4 mmHg, p=0.91	3
m K, 2010 [112]	HTN	102, 98	78, 62	12 months	NU	134.4±14.0	126.3±10.4	132.4±14.7	128.2±13.0	-7.6±11.7 vs. -3.3±12.3 mmHg, p=0.036	2
Allen JK, 2011[122]	DM/HTN/CVD	261, 264	261, 264	12 months	NU + DP	139.7±23.8)	130.8±20.7	138.7±19.9	135.9±20.5	8.9±25.1 vs. 2.7±22.0 mmHg, p=0.003	4
Houweling,	DM	116, 114	102, 104	12 months	NU +	157.5±20.4	(paired	161.3±24.8		7.4 vs. 5.6 mmHg,	1

Author, year	Condition	N Recruited (EG, CG)	N Analysed (EG, CG)	Follow up, mean/range of duration(in months)	Intervention	Mean Systolic blood pressure (±SD)				Mean difference (SE / 95% confidence interval)	Jadad score
						Experimental Group		Control Group			
						Before	After	Before	After		
2011[99]					DP		difference)			p=0.122	
Maungboon P, 2011[83]	HTN	211	211		NU		135		147	135 vs. 147 mmHg, p=0.004	1
Piette JD, 2011[100]	DM	145, 146	145, 146	12 months	NU	136.0±17.0	130.8±17.7	133.8±16.4	134.2±20.6	4.26 mmHg (0.06, 8.5), p=0.05	3
Wakefield, 2011[119]	DM+HTN	93, 102, 107	93, 102, 107	6 months, follow up – 12 months	NU	138(H), 136(L)		134		At 6 months High vs. Low, p=0.06, High vs. control-p=0.004. At 12 months, High vs. Low, p=0.08, High vs. control-p=0.006.	3
Anel-Tiangco, 2012[101]	DM	232, 313	232, 313	24 months	NU		131±15.9		135±18.2	p<0.05	1
Drevenhorn E, 2012[113]	HTN	155, 60	137, 51	24 months	NU + DP	159.1±16.6	142.9±15.1	167±17.6	145.6±10.	NS	1

CG: Control Group; CVD: Cardiovascular diseases; DM : Type 2 Diabetes Mellitus; EG: Experimental Group; HC: Hypercholesterolemia; HTN: Hypertension; MD: Mean Difference; NR: Not Reported; NU: Nurse; NS: Not Significant; NU+DP: Nurse care with Drug Prescription; SBP: Systolic Blood Pressure; SD: Standard Deviation; and SE: Standard Error.

Table 3.4: Effect of nurse-delivered intervention on diastolic blood pressure

Author, year	Condition	N Recruited (EG, CG)	N Analysed (EG, CG)	Follow up, Intervention, mean /range of duration	Intervention	Mean Diastolic blood pressure				Mean difference (SE)/ 95% confident interval	Jadad score
						Experimental		Control			
						Before	After	Before	After		
Logan, 1979 [102]	HTN	232, 225	206, 204	6 months	NU + DP	100.3±0.4	90.3±0.5	100.4±0.4	94.3±0.6	NR	3
McClellan, 1985 [103]	HTN	50, 53	25, 14	12 months	NU + DP	98.6	85.2	103.1	85.8	NS	2
Aubert RE, 1998 [87]	DM (type 1&2)	71(12), 67(5)	100	12 months	NU + DP					DBP decreased in EG and increased in CG 1.9 vs. 6.1 mmHg, p>0.2	2
Mundinger MO, 2000 [120]	DM/HTN	354, 273	211, 145	6 months	NU		82		85	p=0.04	2
Garcia-pena C, 2001 [104]	HTN	364, 354	364, 354	6 months	NU	90.9±10.4		90.8±9.4		3.56 mmHg, p<0.001	4
Gary TL, 2003 [91]	DM	186	(38, 36), (41, 34)	24 months	NU + DP	75 ±12 76 ±15		75 ±11 78 ±11		No difference	3
New JP, 2003[114]	DM+HTN	506, 508	506, 508	12 months	NU + DP	78	74	77	74	-0.79 mmHg (-2.18 to 0.60), p=0.27	4
Guerra Riccio, 2004[105]	HTN	48,52	48, 52	6 months	NU					-21±4 vs. -10±2 mm Hg, p<0.05	2
Krein SL, 2004[92]	DM	123, 123	106, 103	18 months	NU + DP	86 ±12	83 (81 to 86)	86 ±11	83 (81 to 85)	-3 (-5 to-0.06) vs. -3 (-6 to-1) mmHg, p=0.61	3
Rudd P, 2004[106]	HTN	74, 76	69, 63	6 months	NU + DP					6.5±10.0 vs. 3.4±7.9 mm Hg, p<0.05	3
Schroeder K, 2005 [107]	HTN	128, 117	200	6 months	NU	83.7±9.3	80.4±10.1	83. ±9.9	79.9±9.7	0.2 mmHg (-1.9 to 2.3), p=0.85	2
Gabbay RA, 2006 [93]	DM	150, 182	150, 182	12 months	NU + DP	77±10	72±9	77±10	78±10	p<0.001	1

Author, year	Condition	N Recruited (EG, CG)	N Analysed (EG, CG)	Follow up, Intervention, mean /range of duration	Intervention	Mean Diastolic blood pressure				Mean difference (SE)/ 95% confident interval	Jadad score
						Experimental		Control			
						Before	After	Before	After		
Tobe SW, 2006[115]	DM+HTN	50, 49	48, 47	12 months	NU + DP	87.1±8.4	75.5±12.7	84.2±11.1	77.4±11.3	–11.6 (10.6) vs. – 6.8 (11.1) mmHg, p<0.05	3
Artinian NT, 2007 [108]	HTN	194, 193	194,193	12 months	NU	89.5±14.0	83.8±12.1	88.4±13.0	83.5±13.6	-6.3 vs. -4.1 mmHg, p=0.12	4
Hiss RG, 2007[94]	DM	95, 102	81, 83	6 months	NU	76±1.2		73±1.0		–0.96±1.3 vs. 0.65±1.4 mmHg, p=0.39	1
Shibayama T, 2007 [95]	DM	67, 67	66,65	12 months	NU	78±10		76±10		4 (1 to 6) vs. 3 (1 to 6) mmHg, NS	3
Tonstad S, 2007 [109]	HTN	31, 20	29, 16	6 months	NU	94±6	91±8	94±4	92±8	No difference	3
Gary TL, 2009 [96]	DM	269, 273	253, 235	24 months	NU					No difference	4
Brennan T, 2010[111]	HTN	320, 318	320, 318	12 months	NU	84.6±10.9	80.6 ±10.5	83.6 ±12.3	80.1±10.4	p=0.59	3
Chiu CW, 2010[82]	HTN	31, 32	31, 32	2 months	NU	90.48±11.44	78.81±9.08	88.84±11.85	85.12±13.67	11.68 vs. 3.72 mmHg, p=0.004	4
Heisler M, 2010[98]	DM	119, 125	103, 113	6 months	NU	75.8 ±10.7	76.1±10.6	77.1±11.5	76.8±11.9	0.3 vs. -0.3 mmHg, p=0.10	3
Ulm K, 2010 [112]	HTN	102, 98	78, 62	12 months	NU	80.2±9.7	75.0±7.4	78.1±8.9	74.4±8.0	-5.2±7.2 vs. -2.1±7.1 mmHg, p=0.013	2
Allen JK, 2011 [122]	DM/HTN /CVD	261, 264	261, 264	12 months	NU + DP	83.0±12.7	77.4±12.5	82.3±13.0	79.7±12.6	5.6±13.6 vs. 2.6±12.1 mmHg, p=0.013	4
Houweling, 2011 [99]	DM	116, 114	102, 104	12 months	NU + DP	87.2±10.7		87.0±11.2		3.2 vs. 0.3 mmHg, p=0.391	1
Maungboon P, 2011 [83]	HTN	211	211		NU		72		81	72 vs. 81 mmHg, p=0.005	1
Piette JD, 2011 [100]	DM	145, 146	145, 146	12 months	NU	79.8±10.4	76.4±11.4	79.6±11.1	78.2±10.6	p=0.12	3
Anel-Tiangco,	DM	232, 313	232, 313	24 months	NU	80	74	78	74	NR	1

Author, year	Condition	N Recruited (EG, CG)	N Analysed (EG, CG)	Follow up, Intervention, mean /range of duration	Intervention	Mean Diastolic blood pressure				Mean difference (SE)/ 95% confident interval	Jadad score
						Experimental		Control			
						Before	After	Before	After		
2012 [101]											
Drevenhorn E, 2012 [113]	HTN	155, 60	137, 51	24 months	NU	93.0±9.5	83.6±9.3	90.2±11.3	83.1±16.6	NS	1

CG: Control Group; CVD: cardiovascular diseases; DBP: Diastolic blood pressure; DM: Type 2 diabetes mellitus; EG: Experimental Group; HC: hypercholesterolemia; HTN: Hypertension; MD: Mean difference; NR: Not reported; NS: Not significant; NU: Nurse; NU+DP: Nurse care with drug prescription; SD: Standard Deviation; SE: Standard Error

Table No 3.5: Effects of nurse-delivered intervention on blood pressure control/target achievement

Author, year	Condition	N Recruited (EG, CG)	N Analysed (EG, CG)	Follow up, mean/range of duration (in months)	Intervention	Blood pressure control/ target achievement n(Percentage)					Mean difference (SE)/ 95% confident interval	Jadad score
						Target Description	Experimental		Control			
							Before	After	Before	After		
Logan, 1979 [102]	HTN	232, 225	206, 204	6 months	NU + DP	DBP <90 mm Hg[a]		48.5%		27.5%	p<0.001	3
McClellan, 1985[103]	HTN	50, 53	25, 14	12 months	NU + DP	DBP<90 mm Hg		88%		78.6%	NS	2
Garcia-pena C, 2001 [104]	HTN	364, 354	364, 354	6 months	NU	<160/90 mm Hg	29.1	36.5	29.1	6.8	p=0.004	4
Litaker D, 2003 [121]	DM/HTN	79, 78	79, 78	16 months	NU + DP	<130/85 mm Hg		11		10	p=0.839	3
New JP, 2003 [114]	DM+HTN	506, 508	506, 508	12 months	NU + DP	<140/80		26.6%		24.1%	p=0.37	4
Bosworth HB, 2009[110]	HTN	150 144	151 143	24 months	NU	<140/80 <130/85 in DM	36.2±4.8 44.2±5.1	44.9±5.1 32.0±4.6	48.1±8.4 59.5±7.6	43.7±7.7 43.9±7.7	No difference between the groups.	4
Mc Lean DL, 2008 [116]	DM+HTN	115, 112	115, 112	6 months	NU	≤130/80 mm Hg	3(2.6%)	54(47%)	4(3.6%)	37(33.0%)	p=0.02, Odds ratio /95% CI reported	4
MacMohan Tone J, 2009 [117]	DM + HTN/HC	101, 99	94,92	12 months	NU + DP	≤130/ mm Hg ≤80 mm Hg		33% 75.5%		12% 40.2%	33% vs. 12%, p=0.001 75.5% vs. 40.2%, p<0.001	3
Brennan T, 2010 [111]	HTN	320, 318	320, 318	12 months	NU	<120/80 mm Hg	38 (12%)	70(22%)	53(17%)	83(26%)	1.50 (0.991 to 2.27)	3
Chiu CW, 2010 [82]	HTN	31, 32	31, 32	2 months	NU	<140/90 mm Hg		24(75.0)		8(25.8)	p=0.003	4
Houweling, 2011 [99]	DM	116, 114	102, 104	12 months	NU + DP	<140/90 mm Hg	17(16.7)	26(25.5)	19(18.3)	22(21.2)	p=0.629	1
Ishani, 2011 [118]	DM + HTN/H	278, 278	311	12 months	NU + DP	<130/80 mm Hg		40.6%		15.9%	p<0.001	3

Author, year	Condition	N Recruited (EG, CG)	N Analysed (EG, CG)	Follow up, mean/range of duration (in months)	Intervention	Blood pressure control/ target achievement n(Percentage)					Mean difference (SE)/ 95% confident interval	Jadad score
						Target Description	Experimental		Control			
							Before	After	Before	After		
	C											
Maungboon P, 2011 [83]	HTN	211	211		NU	<140/90 mm Hg		71%		49%	p<0.002	1
Piette JD, 2011 [100]	DM	145, 146	145, 146	12 months	NU	<130 mm <80 mm Hg	38% 49%	50% 59%	44% 51%	47% 62%	p=0.53 p=0.13	3
Drevenhorn E, 2012 [113]	HTN	155, 60	137, 51	24 months	NU + DP	≤140/90 mm Hg		72(52.6 %)		20(39.2%)	p=0.13	1

CG: Control Group; CVD: Cardiovascular diseases; DM: Type 2 Diabetes Mellitus; EG: Experimental Group; HC: Hypercholesterolemia; HTN: Hypertension; MD: Mean Difference; NR: Not Reported; NS: Not Significant; NU: Nurse; NU+DP: Nurse care with Drug Prescription; SD: Standard Deviation; SE: Standard Error.

[a] Diastolic blood pressure <90mm Hg in patients with Baseline DBP >95 mm Hg and reduction of 6 mm of Hg in patients with Baseline DBP<95 mm Hg

Table 3.6: Effect of nurse-delivered interventions on HbA1c levels

Author, year	Condition	N Recruited (EG, CG)	N Analysed (EG, CG)	Follow up, Intervention, mean/range of duration(in months)	Intervention	Mean HbA1c				Mean difference (SE)/ 95% confident interval	Jadad score
						Experimental		Control			
						Before	After	Before	After		
Estey AL, 1990 [85]	DM	60	28, 25	4 months	NU	6.3±1.1	5.6±1.1	6.1±1.4	5.8±1.5	0.7±0.9 vs. 0.3±0.7 (NS)	2
Weinberger, 1995 [86]	DM	204, 71	188, 63	12 months	NU	10.7±3.3	10.5±0.2	10.7±3.4	11.1±0.3	10.7±3.4 vs. 11.1±0.3, p=0.046	2
Aubert RE, 1998 [87]	DM (type 1&2)	71(12), 67(5)	71(12), 67(5)	12 months	NU + DP	8.8*		8.4*		-1.7 vs. -0.7, p<0.001	2
Groeneveld Y, 2001 [89]	DM	133, 155	84, 140	12 months	NU		7.1±1.2		7.5±1.8	p=0.06	1
Piette JD, 2001 [90]	DM	146, 146	132, 140 122 (≥8% at baseline) 60 (≥9% at baseline)	12 months	NU	8.2±1.7 9.5±1.3 10.3±1.2	8.1±0.1 8.7±0.2 9.1±03	8.1±1.7 9.2±1.3 10.2±1.5	8.2±0.1 9.2±0.2 10.2±0.3	p=0.3 p=0.04 p=0.04	4
Gary TL, 2003 [91]	DM	186	(38, 36), (41, 34)	24 months	NU + DP	8.8 ± 2.2 8.6 ±1.9		8.4 ±2.0 8.5 ±2.0		No difference except for 1 arm (MD: -0.8±0.52) in a 4 arm trial	3
Litaker D, 2003 [121]	DM/HTN	79, 78	79,78	16 months	NU + DP	8.4±1.4		8.5±1.6		-0.63±1.5 vs. -0.15±1.0, p=0.02	3
Krein SL, 2004 [92]	DM	123, 123	106, 103	18 months	NU + DP	9.3±1.5	9.3 (8.9 to 9.7)	9.2±1.4	9.2 (8.8 to 9.6)	-0.02 (-0.41 to 0.37) vs. -0.16 (-0.53 to 0.22), p=0.61	3
Gabbay RA, 2006[93]	DM	150, 182	150, 182	12 months	NU + DP	7.46±1.4	7.36±1.5	7.45±1.4	7.40±1.8	No difference	1
Tobe SW, 2006[115]	DM+HTN	50, 49	48, 47	12 months	NU + DP	7.7 ±1.8	7.8±2.1	7.7±1.8	7.7±1.9	0.1 (1.7) vs. –0.0 (1.3), p>0.05	3

Author, year	Condition	N Recruited (EG, CG)	N Analysed (EG, CG)	Follow up, Intervention, mean/range of duration(in months)	Intervention	Mean HbA1c				Mean difference (SE)/ 95% confident interval	Jadad score
						Experimental		Control			
						Before	After	Before	After		
Hiss RG, 2007[94]	DM	95, 102	83, 81	6 months	NU	7.7±0.18		7.4±0.18		-0.42±0.15 vs. -0.22±0.17, p=0.39	1
Shibayama T, 2007[95]	DM	67, 67	66,66	12 months	NU	7.3±0.8		7.4±0.7		No difference 0.1 (-0.2 to 0.3) vs. 0.0 (-0.2 to 0.3)	3
Tonstad S, 2007[109]	HTN	31, 20	29, 16	6 months	NU	5.74±0.67	5.62(0.54)	5.58(0.46)	5.64(0.47)	No difference	3
Gary TL, 2009 [96]	DM	269, 273	253, 235	24 months	NU	7.7±2.1		8.0±2.2		-0.20±1.70 vs. -0.08±1.93, p=0.44	4
MacMohan Tone J, 2009 [117]	DM + HTN/HC	101, 99	94,94	12 months	NU + DP	7.1 ± 1.4		7.1 ± 1.4		-0.34 ± 0.1 vs. -0.12 ± 0.1, p=0.013	3
Shea S, 2009[97]	DM	844, 821	844, 821	60 months	NU	7.43±0.05 (SE)	7.09±0.06 (SE)	7.45±0.06 (SE)	7.38±0.06 (SE)	0.29 (0.12, 0.46)	4
Heisler M, 2010[98]	DM	119, 125	103, 113	6 months	NU	7.93±1.40	8.22±1.74	8.02±1.32	7.73±1.32	-0.26 vs. 0.26, p=0.004	3
Nesari M, 2010[84]	DM	30, 31	30, 30	3 months(12 weeks)	NU + DP	8.90±1.44	7.04±1.18	9.60±1.56	8.60±1.88	-1.87% vs. -0.40%, p=0.001	4
Allen JK, 2011[122]	DM/HTN/CVD	261, 264	261, 264	12 months	NU + DP	8.9±2.2	8.3±2.2	8.3±1.9	8.2±2.1	0.6±2.3 vs. 0.1±1.8, MD: -0.5 (-0.9, -0.2) p= 0.03	4
Houweling, 2011[99]	DM	116, 114	102, 104	12 months	NU + DP	7.6 ±1.3		7.4±1.3		Paired difference -0.09 vs. -0.05, p=0.423	1
Piette JD, 2011 [100]	DM	145, 146	145, 146	12 months	NU	7.5±1.7	7.7±1.8	7.7±1.7	7.7±1.7	0.07(-0.26, 0.40), p=0.7	3
Wakefield, 2011[119]	DM+HTN	93 (High intense arm), 102	93, 102, 107	6 months, follow up – 12 months	NU	7.1, 7.2		7.2		At 6 months High vs. control- p=0.02	3

Author, year	Condition	N Recruited (EG, CG)	N Analysed (EG, CG)	Follow up, Intervention, mean/range of duration(in months)	Intervention	Mean HbA1c				Mean difference (SE)/ 95% confident interval	Jadad score
						Experimental		Control			
						Before	After	Before	After		
		(Low intense arm), 107								Low vs. control- p=0.03. At 12 months, No difference between groups	
Anel-Tiangco, 2012[101]	DM	232, 313	232, 313	24 months	NU	8.8	7.8	9.1	8.0	NR	1

CG: Control Group; CVD: Cardiovascular diseases; DM: Type 2 Diabetes Mellitus; EG: Experimental Group; HC: Hypercholesterolemia; HTN: Hypertension; MD: Mean Difference; NR: Not Reported; NS: Not Significant; NU: Nurse; NU+DP: Nurse care with Drug Prescription; SD: Standard Deviation; SE: Standard Error.

*Median values

Table 3.7: Effect of nurse-delivered interventions in glycaemic control

Author, year	Condition	N Recruited (EG, CG)	N Analysed (EG, CG)	Follow up mean/range of duration	Intervention	Glycemic control/target achievement (percentage)					Mean difference (SE)/ 95% confident interval	Jadad score
						Description	Experimental		Control			
							Before	After	Before	After		
Weinberger, 1995 [86]	DM	204, 71	188, 63	12 months	NU	<7.2[a]		8.4%		3.9%	p=0.14	2
Piette JD 2000 [88]	DM	137, 143	124, 124	12 months	NU	<6.5%	8%	17%	7%	8%	MD: 9% (7-30%), p=0.04	3
MacMohan Tone J, 2009 [117]	DM + HTN/HC	101, 99	94,94	12 months	NU + DP	<6.5		52.1%		33%	p = 0.012	3
Houweling ST, 2011 [99]	DM	116, 114	102, 104	12 months	NU + DP	<7.0 <8.5	38(37.3) 79(77.5)	35(34.3) 88(102)	48(46.2) 84(104)	45(43.3) 91(104)	p=0.629 p=0.143	1
Ishani A, 2011 [118]	DM + HTN/HC	278, 278	139	12 months	NU + DP	<8.0		40.5%		24.6%	p=0.047	3
Piette JD, 2011 [100]	DM	145, 146	145, 146	12 months	NU	<8.0	72%	72%	68%	66%	0.11(-0.24, 0.46), p=0.54	3

CG: Control group; CVD: Cardiovascular diseases; DM: Type 2 Diabetes Mellitus; EG: Experimental Group; HC: Hypercholesterolemia; HTN: Hypertension; MD: Mean Difference; NR: Not Reported; NS: Not Significant; NU: Nurse; NU+DP: Nurse care with Drug Prescription; SD: Standard Deviation; SE: Standard Error

3.2 Role of decision-support systems in hypertension/diabetes care

Clinical decision-support systems are defined as '*computer systems designed to impact clinician decision-making about individual patients at the point in time that these decisions are made'* [127]. Computerised decision-support systems (CDSS) are included as a component to disease management interventions to improve care. A systematic review, published in 2005, that assessed both randomised and non-randomised controlled trials to evaluate the effect of CDSS compared with care provided without CDSS on practitioner performance or patient outcomes found that CDSS improved practitioner performance in 62 (64%) of the 97 studies assessing this outcome [128]. Another systematic review of 45 studies that assessed the impact of computerised clinical guidelines on the process of care compared with non-computerised clinical guidelines concluded that computerised clinical guidelines deliver significant improvements in the process of care with 64% of the studies demonstrating a positive effect [129]. Automated provision of recommendation in electronic versions as part of clinician workflow was a significant predictor of positive effect on process of care [129].

The utility of CDSS in chronic disease management is unclear. A three-arm trial in which patients with high blood pressure were randomised to CDSS plus cardiovascular risk chart, cardiovascular risk chart alone or usual care in primary care, covering 27 general practices in Avon, UK, did not find any reduction in CVD risk or systolic blood pressure in the CDSS arm. Instead, the CVD risk chart only group had significantly lower systolic blood pressure compared with the usual care group [130]. On the other hand, a feasibility trial of a CDSS in Australia to assist primary care physicians in assessing CVD risk of patients, found that 77% of the general practitioners were able to understand and agreed with the recommendations for screening and prescriptions generated by CDSS [131]. Further, the study also reported that

the general practitioners found the new tool enabled a systematic approach to care as well as influenced CVD risk communication with patients [131]. The REACH-OUT study, a cluster-randomised trial in nine European countries, used a portable touch screen computer in a physician-implemented CHD risk evaluation / communication programme at primary care level. This trial demonstrated significant mean absolute difference (-18.5%; 95% CI: -35.5 to - 1.4; p = 0.034) in modifiable CVD risk in the intervention clusters, in comparison with usual care clusters at six months [132]. A recent meta-analysis of five studies that examined the effect of CDSS on systolic blood pressure found that CDSS had no benefit in the management and control of hypertension [133].

Similarly, CDSS has also been attempted in diabetes care, as part of quality improvement interventions. Ali et al. carried out a systematic review to assess the quantifiable and qualitative impacts of combined Electronic Medical Record (EMR)-CDSS tools on physician performance and patient outcomes [134]. This review found that improvements in process outcomes associated with EMR–CDSS implementation ranged from no difference to an approximate 30% increase in proportion of patients receiving annual A1C, blood pressure, lipid, foot, urine and eye examinations. The effect on glycaemic control varied from no difference to 1.8% point reduction from baseline, and the A1c reduction was in the range of 0.3–0.9% points over 12 months of follow-up. In addition, a 20% greater achievement of A1C targets was also reported [134].

There is a paucity of studies from developing countries that report effectiveness of electronic decision-support systems on health outcomes. Further, there are practical difficulties in introducing CDSS into developing countries' health systems due to fewer resources available to deploy, maintain and scale-up such tools. Mobile phone technology- based solutions are considered to be a low-cost alternative to CDSS in developing countries, due to their

portability as well as communication and computing capabilities at a much lower cost, owing to their low consumption of power and minimal infrastructure requirement [135, 136]. In addition, due to their computing and communication capabilities, Smartphone-based portable decision-support tools for healthcare personnel could be instrumental in building an organised system of care for hypertension and diabetes care in primary care settings. Potential areas of their application include: computing clinical risk scores for screening (i.e. for diabetes, 10-year risk of CVDs); generating an evidence-based management plan (therapeutic lifestyle, pharmacologic, laboratory investigations and follow-up schedule) tailored to individual subjects; and automated transmission of patient reminders (drug intake and follow-up visits) through short-messaging services. Given the potential of Smartphone-enabled interventions in healthcare, I reviewed the literature for evidence on the effectiveness of Smartphone or electronic handheld-based clinical decision-support systems for the use of healthcare professionals in improving clinical decision-making and process of care.

3.3 Systematic review of Smartphone/handheld device-based decision-support tool-enabled interventions in chronic disease care

3.3.1 Introduction

Interventions involving Smartphones in chronic disease care have been very recent, although these tools have been successfully used in communicable disease programmes for various purposes, such as remote data collection, remote monitoring, epidemic and outbreak tracking, training of health workers and diagnostic and treatment support [137]. Application of Smartphone technology in the non-communicable disease domain is also gaining importance. A meta-analysis on smoking cessation intervention trials, which used text message programmes, showed a significant increase in short-term self-reported quitting, though no effect was demonstrated on long-term outcome [138]. The use of Smartphones as a decision-support system and in patient follow-up has shown encouraging results, particularly in ensuring compliance to medications among patients with diabetes [139]. A systematic review of studies carried out in developed countries found that nine out of 10 studies that measured haemoglobin A1c among people with diabetes reported significant improvement among those receiving education and care support through cell phones [139]. Similarly, self-monitoring of blood pressure and body weight in a weekly web-based diary through the Internet or by cellular phones, along with remote support from the clinic facilities, in a quasi-experimental design has also shown benefits [140]. However, the utility of Smartphone tools or comparable handheld devices in improving clinical decision-making and process of care remains unclear. This review aims to summarise the existing literature in this domain.

3.3.2. Objective

This systematic review aims to synthesise evidence on the effectiveness of Smartphone or electronic handheld-based clinical decision-support systems for healthcare professionals in improving clinical decision-making and process of care.

3.3.3 Methodology

Inclusion and Exclusion Criteria

Type of participants

Participants of any age, involved in a controlled trial in which the healthcare professionals used Smartphone or handheld devices, such as pocket digital assistant (PDA), as a clinical decision-support system in a primary care, hospital or outpatient clinic setting, were included. Studies on models or simulated conditions were excluded.

Type of intervention and control

The review included any intervention that studied Smartphone/ handheld devices, such as pocket digital assistant, as a major or supporting tool for clinical decision-making. Studies that were limited to the use of short-messaging service (SMS) as part of patient management/follow-up/monitoring were excluded. The control group could be usual care or any intervention other than handheld device-based interventions.

Outcome

Primary outcomes were defined as any measure of healthcare service delivery for any length of follow–up or any health outcome.

Information sources

Original papers were searched in MEDLINE via Pub med, EMBASE, OVID, CINAHL and Cochrane CENTRAL databases. In addition, reference lists of all the papers and relevant reviews were manually searched. No authors were consulted for any additional information.

Search Strategy

We searched databases using a strategy including selected MeSH terms and free text terms related to mHealth interventions. The search words and strings used for the search strategy were as follows; Computers, Handheld computer*, handheld computer*, hand-held computer*, palm*, computer*, pocket computer*, mobile pocket-PC*, pocketPC*, pocket computer*, personal digital assistant*, PDA* phone*, tablet PC*, palm-pilot*, palmpilot*, Treo Centro smartbook*, ultra-mobile, ultramobile, ultra-portable, ultraportable, enterprise digital assistant, EDA*, computer* smartphone*, smart-phone*, blackberr*, black-berr*, google phone*, application software, MMS, multimedia messaging service, iphone*, i-phone*, medical informatics, medical informatics applications, audiovisual aids, multimedia, public health informatics, user-computer interface, mobile health NOT van* NOT unit*, mhealth, m-health, video recording, video, video*, internet, WAP, online, web-based, web based, blue tooth, web technolog*, bulletin board*, message board*, interactive health communicat*, interactive technolog*, interactive software, e-health*,

ehealth*, electronic health, consumer health informatics*, nokia, symbion, windows mobile*, INQ, HTC, android, iphone and ipad.

Data Collection Process

Data were extracted from the full text articles retrieved using a piloted, structured data-extraction template, which included data on the participants, intervention, type of study design, duration of the study, follow-up and outcomes.

Quality of individual studies

Quality of individual trials was assessed using Jadad scale, with a maximum possible score of five (two points for descriptions of randomisation, two points for descriptions of double blinding and one point for descriptions of withdrawals) [80].

Summary Measures

Summary measures used in this study were the difference between the study groups and/or odds ratio (categorical variables) as reported.

Synthesis of Results

The search results from the databases were imported into Reference Manager 12.0 software. Two reviewers independently assessed the studies through title screening and abstract screening for including in the review. Differences were resolved through discussion. The

information obtained from data extraction of the selected studies was analysed qualitatively, discussing the effectiveness estimates and the bias for each outcome variable.

Additional Analysis

No additional analysis or meta-analysis was done.

3.3.4 Results

Study retrieval

The search strategy yielded a total of 3385 articles from the databases and an additional 78 articles were identified through manual searching of the systematic reviews and other articles. After the title screening, abstracts of 246 articles were considered for further screening and, from them, 32 full text papers were fully reviewed. From these, 25 papers were excluded as they did not meet the inclusion criteria and the remaining seven studies were included for the qualitative synthesis (Figure 3.8).

Description of the included studies

All the studies were reported from developed nations (three from the USA, two from Canada, and one each from Germany and the UK). The first trial was reported in 2004 and three of the included trials were published in 2009. Out of the seven studies, there were five parallel group RCTs, one cluster RCT and one cross-over trial. The overall sample size of studies was 9040 (EG: 4014 and CG: 5026). The control arm was either usual care or used paper-based protocols/guidelines or textbooks. In one study, PDA without a decision-support software

application was used in the control arm. The total duration of the studies varied from one to 24 months. The mean Jadad score for all studies was 2.857 (maximum score: 5; range: 2-4). While two studies were carried out in an in-patient department (orthopaedic ward and emergency department), the remaining five were from outpatient department settings. A description of the studies included in the review is shown in Table 3.8.

Effects of Smartphone/PDA-based interventions on clinical / process of care outcomes

Out of seven studies included in the final review, one study did not perform any statistical analysis and was excluded from qualitative synthesis. Only one study analysed group difference in a typical manner, i.e. estimates on baseline and post-intervention differences between groups, while the remaining studies reported comparison of the post-intervention differences. The effect estimates reported were mean differences (six studies) and odds ratio (one study). All the trials studied reported process of care-related outcomes while details on clinical outcomes were not reported (Table 3.9).

In total, 19 outcomes were studied in the seven studies. The result showed significant favourable effect in the experimental group for nine outcomes, while five outcomes showed no difference between the groups. No statistical analysis was reported for the remaining five outcomes. A summary of the studies included is given below.

Stengel, et al. studied the effect of introducing a handheld device on the quantity and quality of medical records of an in-patient orthopaedic department, which demonstrated an increase in the median number of diagnoses per patients from four to nine ($p < 0.001$), along with improvement of quality rating of medical records ($p < 0.01$) with respect to correct assessment of a patient diagnosis and prognosis [141]. Similarly, Roy, et al. found that the

use of a PDA based tool to estimate the probability of pulmonary embolism in emergency departments resulted in significantly greater proportion of appropriate diagnostic work-ups and mean number of test per patients in the intervention group [142]. Another trial that assessed the feasibility, patient acceptance and scope of management changes in an emergency department with respect to a PDA based tool, found that changes in clinical management parameters (composite of changes in drug, diagnosis and treatment) were significantly higher in the intervention group (29.8%) compared to the control group (17.6%). [143]

Out of the seven studies, four studies were in the domain of cardiovascular diseases. Greiver, et al. carried out a trial which randomised family physicians, either to receive a handheld device that aided in angina patient evaluation and care or no device for angina patient care. In the intervention group, all the process of care outcomes (overall cardiac stress testing, appropriate use of stress testing, nuclear stress testing, referral to Cardiologist) significantly increased compared to the usual care group [144]. Price, et al. assessed whether PDA-based guidelines improve adherence to five preventive measures in primary care, which included proportion of participants screened for hypertension, pap test, lipid disorder, colorectal-cancer and prophylactic use of Aspirin. Though the results were not statistically tested, the adherence to screening measures were higher in the intervention group [145]. In another trial by Bertoni, et al., 61 primary care practices in North Carolina were randomised, either to receive PDA-based Adult Treatment Protocol III guidelines and Framingham risk scores or to paper-based JNC-7 guidelines. Although the proportion of patients screened and the proportion of patients receiving appropriate prescription were similar in both groups, a significantly higher proportion of participants received appropriate management and had a lower proportion of inappropriate prescription/over-treatment of lipid lowering therapy in the

intervention group [146]. Lee, et al. found that, when advance practice nurses were randomised to use a PDA-based clinical log, with or without decision-support, to diagnose obesity, the obesity-related diagnoses were significantly higher and there was a lower false negative rate (<0.001) in the group which received PDA with a decision-support tool [147]. Since the interventions described above were targeting different disease conditions and outcomes, it was not possible to pool the results to make interpretations.

3.3.5 Discussion

The main finding from this systematic review was that the use of Smartphone/handheld device-based tools in clinical decision making was relatively new and attempted to improve the quality of care by assessing process of care outcomes. Overall, none of the trials were of high quality. They had relatively smaller number of participants and were diverse in the outcomes studied, duration of intervention and the setting where implemented. Out of the total nineteen outcomes studied, the results were mixed and only nine process of care outcomes had significant favourable impact.

Since there were too few similar trials that reported similar outcomes, this review could not judge the utility of Smartphone/ handheld device-based decision-support tools on process of care outcomes. Further, the components of the interventions were also different, as the disease groups studied differed across trials.

Out of the seven studies, four were in the domain of cardiovascular diseases. Although these four studies were diverse, the use of Smartphone/ handheld device-based decision-support tools was attempted for a range of primary care functions, such as preventive screening (of

hypertension, lipid disorders, prophylactic use of Aspirin) [145], management of high cholesterol [146], diagnosis of obesity [147] and management of angina patients [144]. None of the trials reported deterioration of process of care outcomes in the intervention arm compared to the control arm. Therefore, it is plausible that such interventions may be useful in primary care settings. However, they need further evaluation in larger trials, in different countries. The findings of this review are also consistent with a recent systematic review by Free, et al. which reported high diversity in the components of interventions and outcomes of various trials to pool the results to make meaningful interpretation of the studies [148].

This review could not find any published literature from developing countries. None of the studies reported the steps that were adopted to integrate the interventions to routine care delivery at the health facilities. Further, none of the studies reported information on overall time spent towards additional efforts on the intervention components and the acceptance of healthcare professionals, if it demanded more of their time. The trials also did not report the cost of the customised Smartphone-based software applications and additional infrastructure required for the intervention.

The methodological quality of the trials was very poor. All the trials included in this review had high risk of bias as there was no allocation concealment and, hence, there could be overestimation of the effects. A similar view was also echoed in other systematic reviews [139, 148–150] and is claimed to be a major obstacle to scaling-up of such innovations [151], resulting in calls for more emphasis on evaluation to ensure that these systems are safe, beneficial and cost-effective [137, 152, 153].

Limitation of the review

This systematic review attempted to cover all interventions that attempted Smartphone/handheld device-enabled interventions aimed at improving process of care and, hence, could not focus on specific process or health outcomes. The outcomes were diverse and, hence, no meta-analysis could be attempted. The results from this review need to be interpreted with caution, as all the studies included were from developed countries, and were of limited numbers.

3.3.6 Conclusion

This review highlights the paucity of evidence on Smartphone/handheld device-enabled interventions in clinical decision-making in primary care settings. Hence, more robust evaluation of mHealth interventions is warranted to conclude their utility in improving quality of care in primary care settings.

Table 3.8: Description of the studies included in the review

First author, Year	Country	Type of study	Participants and clinical settings	Sample Size			Age (Mean/range)			Intervention		Total Duration of the Study (months)
				EG	CG	Total	EG	CG	Total	Experimental Group (EG)	Control Group (CG)	
Stengel D, 2004[141]	Germany	RCT	4 physicians and 2 students provided care to 80 patients in Inpatient orthopaedic ward	39	39	78	49.5	46.8		Handheld computer	Conventional care	1
Greiver M, 2005[144]	Canada	RCT	18 family physicians, 76 patients aged 30-75 years with possible new-onset angina	37	28	65			30-75	Handheld computer	Usual care with no device	7
Price, 2005[145]	Canada	RCT	8 general practitioners, 79 patients requesting routine preventive health visits	40	39	79	52.4	60.7	-	PDA with palm prevention application	PDA	2
Rudkin, 2006[143]	USA	Crossover RCT	63 Emergency medical residents.	181	131	312				PDA	Text guide of general disease.	3
Bertoni AG, 2009 [146]	USA	Cluster RCT	Cholesterol management program in 61 primary care practices randomized (32, 29)	2216 (2010)	2841 (1811)	5057	47.6	46.9		PDA with ATP III guidelines	Training materials on JNC-7 guidelines	24
Lee NJ., 2009[147]	USA	RCT	Obesity related diagnosis in 1874 patients by 29 nurses.	807	997	1804	47.8	47.16		PDA	No device	8
Roy P, 2009[142]	Uk	RCT	42 nurses from 20 emergency departments	694	951	1645	57.2	63.2		DSS activated in the handheld devices	Used posters & pocket cards that showed diagnostic strategies.	7

ATP-III: Adult Treatment Panel –III; CG: Control Group; DSS: Decision Support System; EG: Experimental Group; JNC-7: Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7); PDA: Pocket Digital Assistant; RCT: Randomized Control Trial

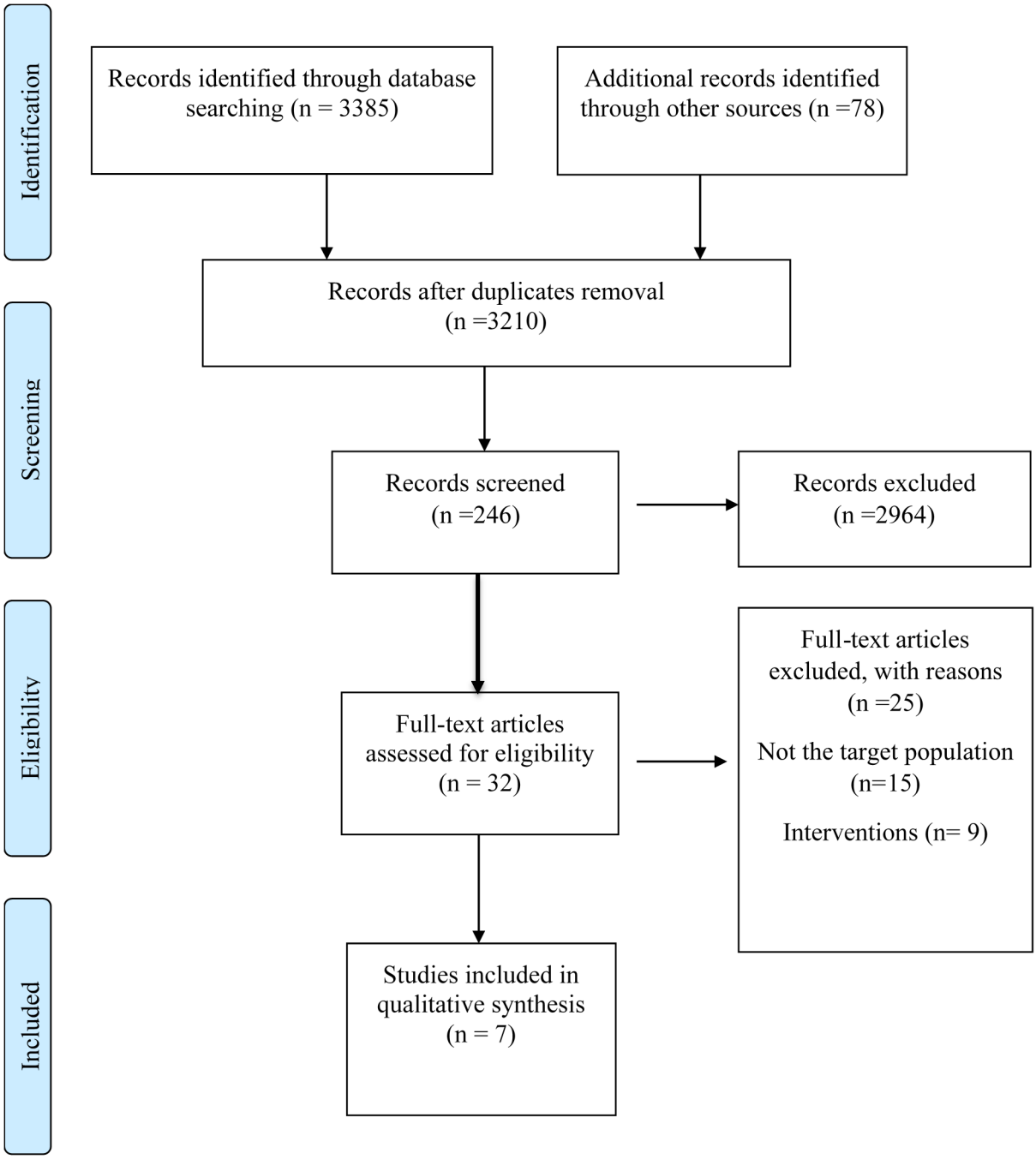
Table 3.9: Effects of smartphone/handheld device enabled interventions on outcomes in health care

Author, Year	Description	Participants and setting	Intervention and control	Outcome	Changes in Outcome		Effect estimates EG, CG)	Jadad score
					EG	CG		
Stengel D , 2004 [141]	RCT to test whether a handheld device could improve both quantitative and qualitative aspects of medical records	80 Patients (39, 39, analyzed) admitted in inpatient orthopaedic ward	Handheld computer vs. Paper forms	Number of diagnoses per patients	Mean: 3.3±1.8	Mean: 3.3±1.8	Median - 9 (IQ 6-14) vs. 4 (IQ 3-5), p<0.001	3
Greiver M, 2005 [144]	Family physicians were randomized to PDA or Usual care group to assess the process of care in angina patients.	18 family physicians, 76 patients (65 analysed: 37 vs. 28) with possible new-onset angina	Handheld computer vs. Usual care	Overall Cardiac stress testing Appropriate use of stress testing Nuclear stress testing Referral to Cardiologist	81% 48.6% 63.5% 38.2%	50% 28.6% 45.5% 40.9%	31%, (95% CI: 8 - 58%, p=0.007). 20% (95% CI -11.54 - 51.4%, p=.284). 17.5% (95% CI: 13.9 - 48.9%, p=.400). NS, p=0.869	2
Price M 2005[145]	Examined PDA based guidelines improved adherence to 5 preventive measures in primary care	79 patients (40, 39) requesting routine preventive health visits	PDA vs. No device	Percentage of participants screened for hypertension Pap test lipid disorder colorectal-cancer Prophylactic use of Aspirin	 94% 100% 94% 65% 81%	 97% 88% 64% 38% 33%	 No statistical analysis done.	3
Rudkin SE, 2006 [143]	Assessed feasibility and patient acceptance of PDA and to determine the scope of management changes.	295 patients cared by 63 Emergency medical residents	PDA vs. Text guide of general disease	changes in management (composite of changes in drug, diagnosis and treatment)in percentage	29.8%	17.6%	Odd ratio (95%CI) =2.00 (1.11-3.60)	2
Bertoni AG, 2009 [146]	Primary care practices were randomized to receive either PDA which provide ATP III guidelines and Framingham risk scores or to JNC-7 guidelines (Paper).	Cholesterol management program in 61 primary care practices randomized (32, 29)	PDA + ATP III guidelines vs. training on JNC -7 guidelines	Patient Screened Appropriate Management Inappropriate Prescription/ over treatment of lipid lowering therapy Patient received appropriate prescription	43.6 vs. 49.0 73.4 vs. 72.3 6.6 vs. 3.9 38.8 vs. 24.8	40.1 vs. 50.8 79.7 vs. 68.9 4.2 vs. 6.4 45.3 vs. 24.1	-5.3, p=0.22 +9.7, p<0.01 -4.9, p<0.01 +7.2, p<0.37	4

Author, Year	Description	Participants and setting	Intervention and control	Outcome	Changes in Outcome		Effect estimates EG, CG)	Jadad score
					EG	CG		
	Random samples of medical records were collected from the primary care practices.							
Lee NJ, 2009[147]	Advance practice nurses were randomized to PDA based clinical log with or without decision support to diagnose obesity.	Obesity related diagnosis in 1874 patients by 29 nurses (807, 997)	PDA based log vs. no device.	Obesity related diagnosis in clinical encounters. False negative rate	11.3% 24.5%	1% 66.5%	p =<0.001 p=<0.001	2
Roy P, 2009[142]	Emergency departments were randomized and physicians in the PDA group used PDA to generate a Geneva score and an estimate of the probability of pulmonary embolism.	1645 consecutive outpatients with suspected pulmonary embolism (694,951)	DSS activated on PDA vs. Used posters and pocket cards	Appropriate diagnostic work-ups Number of test per patient.	30.2% 1.76 ±0.98	10.9% 2.25±1.04	Mean Difference = 19.3% (2.9 to 35.6%), p=0.023 p<.001.	4

ATP-III: Adult Treatment Panel –III; CG: Control Group; DSS: Decision Support System; EG: Experimental Group; EMR: Electronic Medical Record; ICU: Intensive Care Unit; JNC-7: Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7); PDA: Pocket Digital Assistant; RCT: Randomized Control Trial

Figure 3.8: Flow diagram for systematic review of the literature on Smartphone/ handheld device-based decision-support interventions in chronic disease care



Reasons for excluding 2964 records from systematic review:
After duplicates removal, the title and abstract of all the articles were screened for their eligibility to be included in the review in accordance with the inclusion and exclusion criteria as described in the methodology. The abstracts were screened for PICO (Population, Intervention, Comparator and Outcome), study design (description in the abstract indicating whether the study was a randomized controlled trial) and the study setting (primary health care, tertiary care, in-patient care, community based) in order to select qualifying papers for review. While screening abstracts, care was taken not to miss any potential papers by going to full text whenever required. Articles were excluded only when there was evidence in the title or abstract, to conclude that, the paper was of not of interest. Following this rule 2964 articles were excluded through screening, which were not meeting the inclusion criteria.

SECTION B

Outline of the section

This section has only one chapter. This chapter elaborates the conceptual framework followed in the development of the intervention and briefly describes the overall methodology for this research. The detailed methodology for each of the research activities are given in Section C along with results.

Chapter 4: Methods

4.1 Aim and objectives of the PhD

The aim of this research was to design a feasible and scalable, evidence-based, Smartphone-enabled, healthcare delivery service for the management of hypertension and diabetes in the primary healthcare facilities of India.

4.2 Objectives

The specific objectives were:

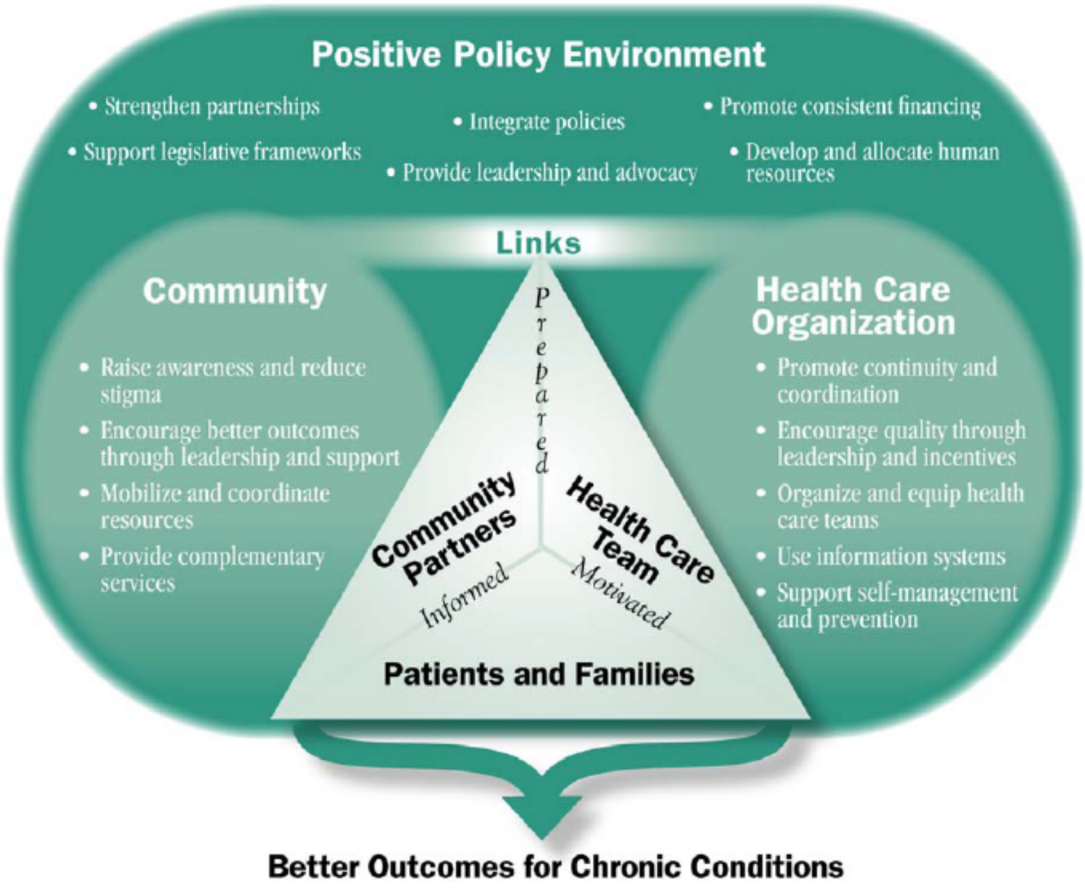
1. To conduct a healthcare facility assessment to inform the development of a Smartphone-enabled intervention package for hypertension and diabetes at primary healthcare facilities in India
2. To pilot the Smartphone-enabled hypertension and diabetes intervention package at primary healthcare facilities in India in order to identify the barriers, synergies and health system strengthening requirements for the feasibility and scalability of such an intervention.

4.3 Conceptual framework

The World Health Organisation has proposed an Innovative Care for Chronic Conditions (ICCC) Framework to improve the care of chronic conditions [154]. The ICCC Framework is comprised of fundamental components within the policy (macro-), healthcare organisation and community (meso), and patient (micro) levels [154]. These components are described as "building blocks" that can be used to create or redesign a healthcare system to more

effectively manage long-term health problems such as hypertension or diabetes. The ICCC Framework is centred on a healthcare triad, which is formed out of three elements: healthcare teams, the patients and families and community partners (Figure 4.1). The triad functions at its best when every member is informed, motivated and prepared to manage chronic conditions, and communicates and collaborates with the others members of the triad. The triad is influenced and is supported by the larger Health Care Organisation (HCO), the broader community and the policy environment. This framework illustrates that creating better outcomes for chronic conditions is complex and involves multiple actors and interacting pathways.

Figure 4.1: WHO Innovative Care for Chronic Conditions (ICCC) Framework

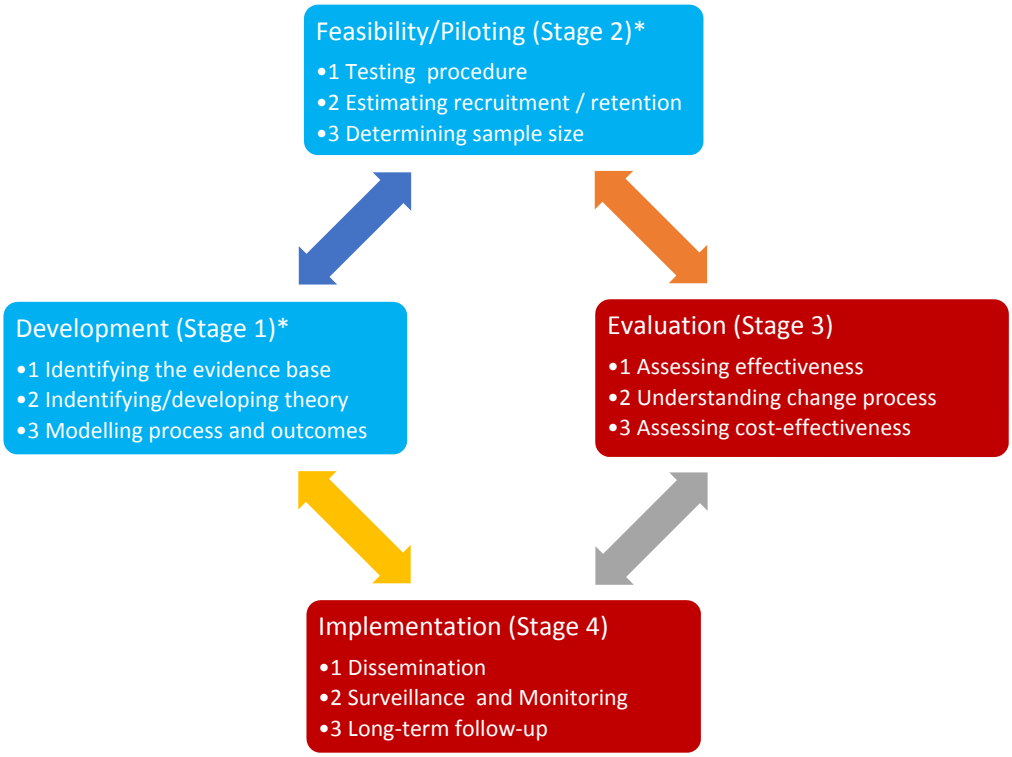


This research work focuses at the level of Health Care Organisation (HCO) and, specifically, on two elements, namely: 1) to organise and equip the healthcare team, and 2) the use of information systems with an aim to develop an intervention package for hypertension and diabetes at primary care settings in India.

The Medical Research Council (MRC) framework that guides '*the development and evaluation of RCTs for complex interventions to improve health'* describes that there are four iterative stages in the development of complex interventions: development (stage 1), feasibility/piloting (stage 2), evaluation (stage 3) and implementation (stage 4). See Figure 4.2.

This research work involves the first two stages of developing a Smartphone-enabled intervention package for diabetes and hypertension suitable to be taken further for a definite cluster randomised trial for evaluation (Figure 4.2).

Figure 4.2: Key elements of the development and evaluation process of complex intervention-MRC Framework



Source: [155]

**This research involves stages 1 &2, shaded in blue*

In order to develop the intervention, a review of literature spanning the areas of development of complex interventions, implementation science and evaluation methods was carried out to derive a conceptual framework that would guide this entire research work. In 2004, Fleuren, et al. proposed a conceptual framework [156] presenting the main stages in innovation processes in health and related categories of determinants, based on the *Theory of Innovation Dissemination* [157] and several related theories and models. According to Fleuren, et al.'s framework, development of an intervention, *which is an innovation*, needs to pass through the

four main stages in innovation processes, namely: 1) adoption; 2) implementation; 3) continuation; and 4) dissemination. The stages are iterative, as the innovation evolves and the transition from one stage to next stage can be affected by various determinants. These determinants can be divided into: 1) characteristics of the socio-political context; 2) characteristics of the organisation; 3) characteristics of the user of the intervention (healthcare team); and 4) characteristics of the intervention [156]. Among these determinants, the healthcare team and the characteristics of the intervention play crucial roles in the innovation process. Further, the healthcare professional does not work in isolation and is part of an organisation, which, in turn, is part of a larger environment. Therefore, the characteristics of the organisation and the socio-political context in which the organisation operates should also be taken into account [156]. A detailed list of determinants is shown in Table 4.1.

The above described framework of Fleuren, et al. was adapted and modified to form the conceptual basis in developing and piloting this intervention. Fleuren's framework does not explicitly describe the formative stages of the development of the intervention, which is crucial and involves considerable groundwork. Hence, it was modified to include the formative stage of the intervention that comprises needs assessment, conceptualising the contours of the intervention and securing permissions from the authorities to conduct the piloting of the intervention within the health system (see Figure 4.3).

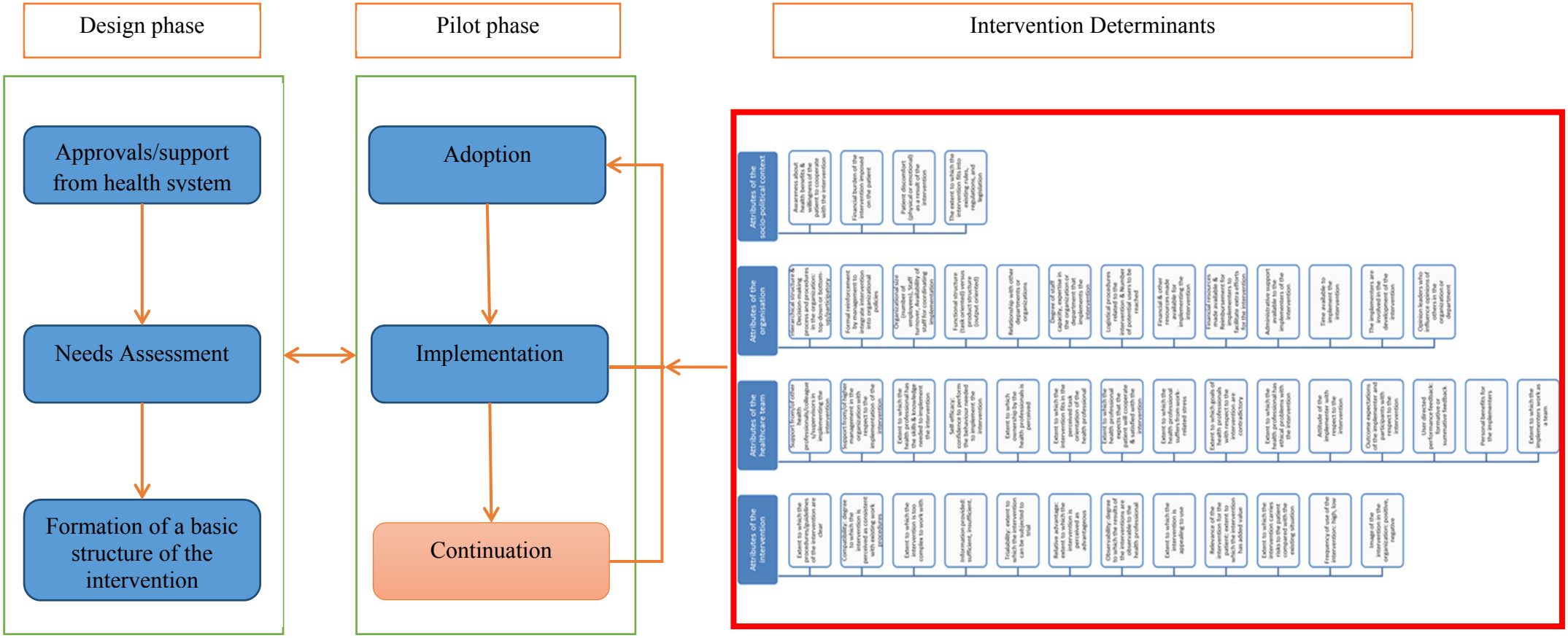


Figure 4.3: Diagrammatic representation of conceptual framework used in this research work

Note: See Table 4.1 for clear description of Intervention determinants

Table 4.1: Determinants of the Implementation process

Type of Determinants	Description of Determinants
Socio-political context	Willingness of the patient to cooperate with the innovation
	Degree to which the patient is aware of the health benefits of the innovation
	Patient doubts concerning the health professional's expertise and competence with respect to the innovation
	Financial burden of the innovation imposed on the patient (e.g. no insurance coverage)
	Patient discomfort (physical or emotional) as a result of the innovation
	The extent to which the innovation fits into existing rules, regulations and legislation
Organisation	Decision-making process and procedures in the organisation: top-down or bottom-up/participatory
	Hierarchical structure: extent to which the decision-making process is formalised through hierarchical procedures
	Formal reinforcement by management to integrate innovation into organisational policies
	Organisational size (number of employees): large, medium, small
	Functional structure (task oriented) versus product structure (output oriented)
	Relationship with other departments or organisations: introvert or outreaching
	Nature of the collaboration between departments involved in the innovation
	Staff turnover: high, average, low
	Degree of staff capacity in the organisation or department that implements the innovation
	Available expertise, in relation to the innovation in the organisation or department
	Logistical procedures related to the innovation, e.g. logistical problems in scheduling patients
	Number of potential users to be reached: many, few
	Financial resources made available for implementing the innovation
	Reimbursement for implementers/organisations to facilitate extra efforts in applying the innovation
	Other resources made available for implementing the innovation (e.g. equipment, manuals)
	Administrative support available to the implementers of the innovation
	Time available to implement the innovation
	Availability of staff responsible for coordinating implementation in the organisation
	The implementers are involved in the development of the innovation
	Opinion leaders who influence opinions of others in the organisation or department
Adopting person/user	Support from/of colleagues in implementing the innovation
	Support from/of other health professionals in implementing the innovation
	Support from/of their supervisors in the department/organisation with respect to the implementation of the innovation
	Support from/of higher management in the organisation with respect to the implementation of the innovation
	Extent to which colleagues implement the innovation (modelling)
	Extent to which the health professional has the skills needed to implement the innovation
	Extent to which the health professional has the knowledge needed to implement the innovation
	Self-efficacy: confidence to perform the behaviour needed to implement the innovation
	Extent to which ownership by the health professionals is perceived. Extent to which the innovation fits with the perceived task orientation of the health professional
	Extent to which the health professional expects that the patient will cooperate in the innovation

	Extent to which the health professional expects that the patient will be satisfied with the innovation
	Extent to which the health professional suffers from work-related stress
	Extent to which goals of health professionals with respect to the innovation are contradictory
	Extent to which the health professional has ethical problems with the innovation
	Attitude of the implementer with respect to the innovation
	Outcome expectations of the implementer and participants with respect to the innovation
	Perceived social norm with respect to the innovation by colleagues and supervisors
	User-directed performance feedback: formative or summative feedback
	Personal benefits for the implementers
	Extent to which the implementers work as a team
Innovation	Extent to which the procedures/guidelines of the innovation are clear
	Compatibility: degree to which the innovation is perceived as consistent with existing work procedures
	Complexity: extent to which the innovation is too complex to work with
	Information provided: sufficient, insufficient.
	Trialability: extent to which the innovation can be subjected to trial
	Relative advantage: extent to which the innovation is perceived as advantageous
	Observability: degree to which the results of the innovations are observable to the health professional
	Extent to which the innovation is appealing to use
	Relevance of the innovation for the patient: extent to which the innovation has added value
	Extent to which the innovation carries risks to the patient compared with the existing situation
	Frequency of use of the innovation: high, low
	Image of the innovation in the organisation: positive, negative

Source: Fleuren et al., 2004 [156]

4.3.1 Description of the conceptual framework in the context of developing an intervention for hypertension and diabetes

Healthcare interventions in hypertension and diabetes are generally complex in nature, comprising several components that interact with each other as well as with their complex contextual factors. Hence, designing an intervention for hypertension and diabetes needs to consider several factors that influence the healthcare team within the Health Care Organisation (HCO) to make a difference in health outcomes. While designing, the intervention passes through different phases before it is ready for testing for effectiveness in a controlled trial.

4.3.1.1 Design phase

During the design phase the conceptualisation and contours of the intervention and its components are mostly derived through literature review and expert consultation. Subsequently, necessary permissions and support are sought from the health system authorities to carry out a needs assessment exercise and piloting the intervention. A needs assessment exercise needs to be carried out at different levels, such as health system, healthcare team and patients. Further, the needs assessment also needs to gather information on various barriers and facilitators that operate at different levels. With inputs from needs assessment, necessary modifications are made in the design of the intervention before it is ready to be piloted.

4.3.1.2 Feasibility/Pilot phase

A newly designed intervention is considered as an innovation. According to Fleuren, et al.'s framework, which is based on the *theory of diffusion of innovations*, an intervention has to pass through the three stages (i.e. adoption, implementation and continuation). *Adoption* refers to the proportion of healthcare facilities and the healthcare team who will adopt the intervention. *Implementation* is the extent to which the intervention has been implemented by the healthcare team and received by the intended study participants. *Continuation* is the extent to which the intervention is sustained over time and has become part of the norm and everyday culture of the healthcare organisation.

4.3.1.3 Determinants of the implementation process of an intervention

According to Fleuren's framework, the implementation process of an intervention is affected by four main categories of implementation determinants that could either facilitate or hamper implementation, which include: 1) Attributes of the socio-political context; 2) Attributes of the healthcare organisation; 3) Attributes of the intervention; and 4) Attributes of the

adopting healthcare team members [156]. A detailed list of determinants that affect the implementation process is shown in Table 4.1

Attributes of the socio-political context that affect the implementation process of the intervention include such factors as awareness about health benefits and willingness of the patient to cooperate with the intervention; financial burden of the intervention imposed on the patient; patient discomfort as a result of the intervention; and the extent to which the intervention fits into existing rules, regulations and legislation, etc. [156].

Similarly, the attributes of the healthcare organisation that affect the implementation process of the intervention include hierarchical structure and decision-making process and procedures in the organisation; formal reinforcement by management to integrate intervention into organisational policies; availability of staff for coordinating implementation; functional structure; relationship with other departments or organisations; degree of staff capacity; expertise in the organisation that implements the intervention; logistical procedures related to the intervention; number of potential users to be reached; financial and other resources made available for implementing; administrative support available to the implementers of the intervention; time available to implement the intervention; whether the implementers are involved in the development of the intervention; and opinion leaders who influence the opinions of others in the organisation, etc. [156].

The major attributes of an intervention that influence the implementation process of the intervention by the healthcare team are its relative advantage, compatibility, trialability, observability and complexity [156]. The *relative advantage* of an intervention is the degree to which it is perceived as better than that which it precedes. In order to be successful, the new intervention needs to be perceived by the healthcare team as having a relative advantage over the existing process of care. *Compatibility* compares whether the new intervention over the

existing delivery fits with the existing values, past experiences and needs of the healthcare team. Experimentation with the new intervention by the healthcare team is an indication of its *trialability*. *Observability* refers to the extent to which the achievements of the intervention are seen, while *complexity* is the degree to which the intervention is considered as complex and difficult to use by the healthcare team.

The attributes of the healthcare team that influence the implementation process include support from/of other health professionals/colleagues/supervisors in implementing the intervention; support from/of higher management in the organisation; extent to which the health professional has the skills and knowledge needed to implement the intervention; self-efficacy; the extent to which ownership by the health professional is perceived; extent to which the intervention fits with the perceived task orientation of the health professional; extent to which the health professional expects that the patient will cooperate and be satisfied with the intervention; extent to which the health professional suffers from work-related stress; extent to which goals of health professionals with respect to the intervention are contradictory; user-directed performance feedback; personal benefits for the implementers; extent to which the implementers work as a team, etc.

4.3.1.4 Evaluation of the implementation process of the pilot intervention

During implementation of the pilot intervention, it passes through three stages, as described in the innovation theory used in Fleuren, et al.'s framework. The evaluation components for each of the stages vary greatly depending upon the nature of the intervention and the setting where it is applied. However, neither the Theory of Diffusion of Innovation nor Fleuren, et al.'s framework provides any specific strategies or guidelines for evaluating the implementation process of an intervention, particularly due to wide variation in the organisation context in which interventions are implemented. However, Wierenga, et al. and Bakken, et al. have described several evaluation components for implementation stages,

combining several evaluation frameworks, including the Re-AIM framework [158, 159]. Wierenga, et al. developed specific evaluation components for each stages of a worksite lifestyle intervention while Bakken, et al. developed various evaluation questions for evaluating decision-support-enabled, guideline-based clinical informatics interventions. These are extremely useful tools to guide in developing evaluation components that vary with the type of interventions and the setting where it is applied. I adapted and modified the evaluation components developed by Wierenga, et al., drawing inputs from Bakken, et al. and factoring in the characteristics of the intervention, for evaluating different stages of implementation relevant for the three different levels (i.e. healthcare organisation, healthcare team and patient) where the actual implementation process operates [159]. The definitions of the evaluation components to be assessed for each of the stages of implementation process are shown in Table 4.2.

Table 4.2: Definition of evaluation component at different levels and data collection method

Stages of intervention development	Definition of evaluation component at different levels	Data collection method
Adoption	Healthcare organisation level	
	Sources and procedures used to approach and involve the health system administrators/ management for their support and to become effective members of the project	Observation, In-depth interviews
	Healthcare team level	
	Sources and procedures used to approach and involve the healthcare team to become effective members of the intervention project	Observation, In-depth interviews
	Patient level	
	Sources and procedures used to inform and involve patients for participation in interventions	Observation, In-depth interviews
Implementation	Healthcare organisation level	
	Providing the intervention to the health facilities and members of the healthcare team	Observation, In-depth interviews
	Healthcare team level	
	▪ Numbers of the healthcare team approached as members of the intervention project; ▪ Numbers of the healthcare team who received training on the intervention; ▪ Opinion/satisfaction about the intervention and its components by the healthcare team ▪ Compliance to DSS-based clinical management plan; ▪ Effect of the intervention on outcome indicators	Observation, In-depth interviews; Assessment of hospital records
	Patient level	
	▪ Proportion of patients who received the intervention, including follow-up care ▪ Opinion/satisfaction of patients about the intervention	Observation, In-depth interviews, Assessment of hospital records
Continuation	Healthcare organisation level	
	Extend to which the interventions became routine and part of the everyday culture and norms of the organisation, including the degree to which interventions are continued.	Observation, In-depth interviews, Assessment of hospital records
Implementation determinants	All levels	
	1. Attributes of the socio-political context 2. Attributes of the organisation 3. Attributes of the healthcare team members 4. Attributes of the intervention	Observation, In-depth interviews

Adapted and modified from Bakken et al., 2009 & Wierenga et al., 2012 [158, 159]

4.4 Methodology

This research work was part of a larger project, namely the mPower-Heart Project, implemented by the Centre for Chronic Disease Control (CCDC), New Delhi, India, in collaboration with the All India Institute of Medical Sciences (AIIMS), New Delhi, and the Government of Himachal Pradesh, India. The Principal Investigators of mPower Heart Project are Prof. D. Prabhakaran (Executive Director, CCDC) and Prof. Nikhil Tandon (Professor of Endocrinology & Metabolism, Department of Endocrinology, AIIMS). The project was implemented in the Solan district of Himachal Pradesh. I was affiliated with CCDC as Senior Research Fellow at the time of enrolling for a PhD at the London School of Hygiene & Tropical Medicine, with the support of a fellowship from the Public Health Foundation of India. My role in the mPower Heart project was as Project Coordinator. A project steering committee, comprising the Principal Investigators from CCDC (Prof. D Prabhakaran), AIIMS (Prof. Nikhil Tandon), the Chief Medical Officer of Solan District (Dr. M K Sharma) and the Project Coordinator, oversaw the implementation of the mPower Heart Project.

4.4.1 Methods overview

The study employed a mixed methods approach to evaluation of the intervention design and implementation using predominantly qualitative data and supported by quantitative data. The starting point for choosing an appropriate methodology for designing the intervention was through expert consultation. The method for the design phase of the intervention was predominantly through in-depth interviews, supported by quantitative methods.

For the evaluation of the pilot, a qualitative process evaluation using a nested analytical framework was developed based upon the conceptual approach of Fleuren, et al. [156] on the innovation process and related categories of determinants within healthcare organisations.

The detailed methodology of each stage of the intervention development and implementation is described in detail in Chapters 5 and 8.

4.4.1.1 Methods for the design phase of the intervention

The design phase started by reviewing the literature to identify various barriers for delivering care for hypertension and diabetes in primary care settings in India, and various interventions that seek to improve the process of care, including decision-support tools that make use of Smartphone technology. Three manuscripts from the above literature review have been published [136, 160, 161]. The first paper describes the scope of Smartphone technology in diabetes interventions (Appendix-1) while the second paper reviews the scope of Smartphone technology in tobacco cessation interventions (Appendix-1). The third paper delineates themes of clinical research to strengthen the healthcare organisation in India in delivering high quality cardiovascular healthcare (Appendix-1).

4.4.1.1.1 Methods adopted for needs assessment

Quantitative methods

Needs assessment was carried out at the selected health facilities through a Health Facility Assessment (HFA) tool developed out of *Indian Public Health Standards for Community Health Centres revised in 2010* [162]. The tool covered facility assessment in four domains (Service Delivery, Manpower, Equipment and Drugs) in relation to capacity for hypertension and diabetes care (see Appendix-2).

Qualitative methods

In addition to HFA, in-depth interviews (IDIs) with various stakeholders in the healthcare organisation were carried out. Further, observation of the functioning of the hospitals and assessment of the records of the health facility were also made. The themes for the IDIs were based on the objectives of the study. The detailed methodology is described in Chapter 5.

4.4.1.1.2 Design of the intervention

Subsequent to the literature review and needs assessment exercise, consultations with experts from the fields of cardiology, diabetology and health administration were carried out to outline the contours of the intervention. The Project Steering Committee approved the outline of the intervention I developed from the above process and oversaw the development of a clinical management guideline for hypertension and diabetes and a decision-support software tool (DSS) for the use at CHCs.

4.4.1.2 Methods for evaluation of the pilot phase

The piloting phase started when the design of the intervention was completed and preparation, such as training modules and decision-support software tools, were ready and recruitment of staff and training of the healthcare team was completed. Mixed methods were chosen for evaluating the implementation of the pilot with respect to the evaluation components described earlier (Table 4.2).

4.4.1.2.1 Quantitative component

The quantitative component of the study was focussed on collecting data to design a definite randomised control trial for the next step. Data pertaining to the following outcomes were collected during the pilot:

1. Number of patients attending the out-patient department (OPD) eligible for opportunistic screening
2. Number of known cases of hypertension / diabetes attending the OPDs
3. Number of new cases detected through opportunistic screening
4. Mean change in systolic blood pressure at six months of follow-up from the baseline
5. Mean change in fasting glucose level at six months of follow-up from the baseline

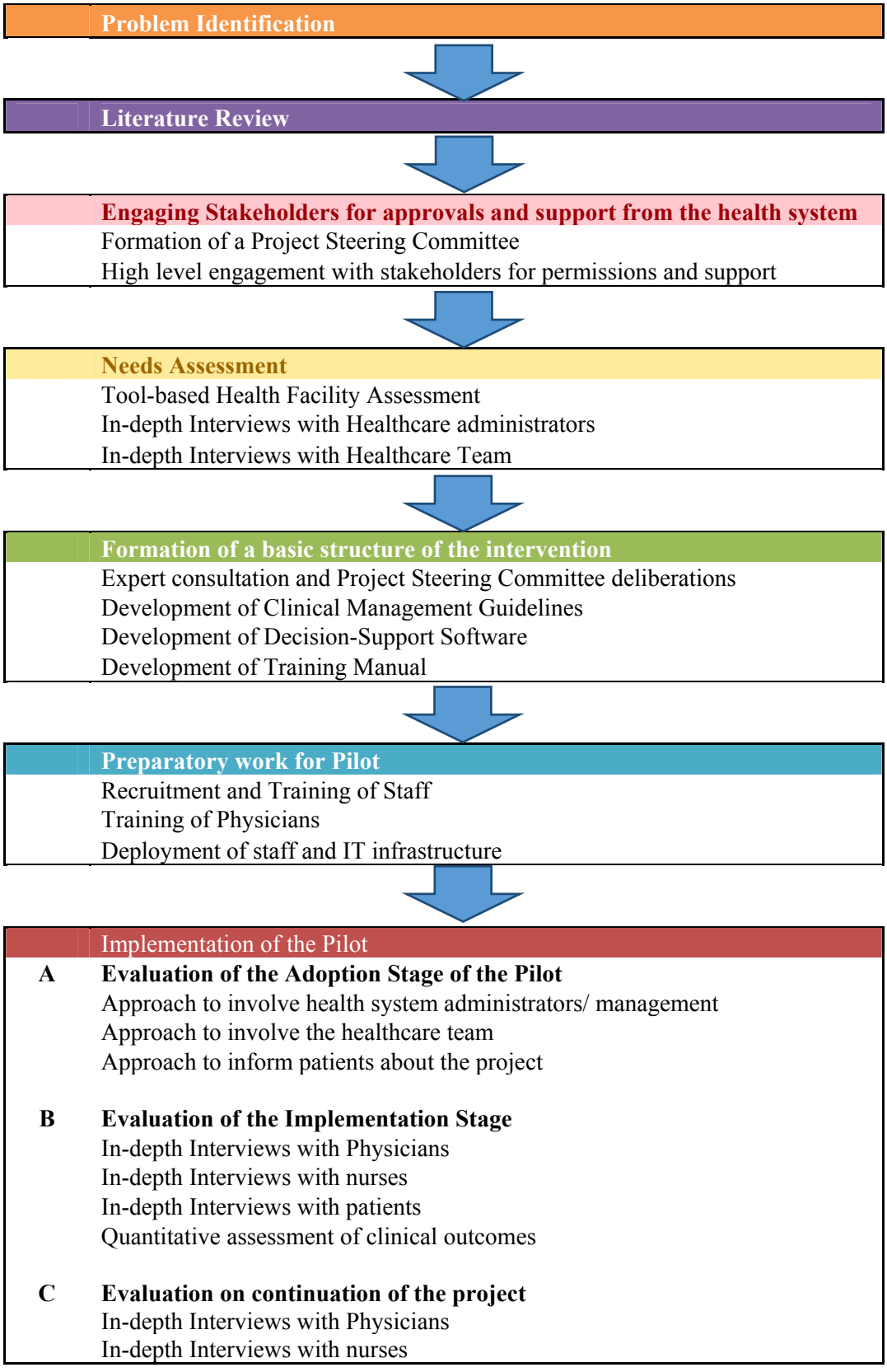
6. Follow-up rate achieved for hypertension and diabetes patients at three months from the baseline

Along with this, quantitative data was collected from the records of the health facilities, such as supply of drugs and prescriptions patterns, to supplement the analysis and interpretation of the data.

4.4.1.2.2 Qualitative component

The qualitative component of the study was designed to collect the feasibility and acceptability of the intervention through in-depth interviews and observation of the implementation of the intervention. The in-depth interviews were conducted with the healthcare team and the patients who were part of the intervention. The themes for the IDIs were based on the conceptual framework and evaluation methodology described earlier. The definition of evaluation component for each of the stages of in the process of implementation is given in Table 4.2. An overview of the sequential steps in the research carried out during the development and implementation of the intervention package in shown in Figure 4.4.

Figure 4.4: An overview of the sequential steps in the research carried out during the development and implementation of the intervention package



4.5 Timeline of project

The project started with a design phase, which commenced in February 2012, seeking necessary approvals from the government and conducting the needs assessment through health facility assessment. In addition, training manuals and decision-support software were developed during this phase. During September – November 2012, preparatory works were carried out, such as training of Medical Officers, recruitment and training of Nurse Care Coordinators (NCC), and pilot testing of the decision-support system software. (Table 4.3).

Table 4.3: Timeline of the project

Name of the phases	Timeline
Design phase	Feb 2012 – Aug 2012
Preparation phase	Sep 2012 – Nov 2012
Pilot implementation & evaluation	Dec 2012 – July 2013

Trial Registration:

- www.clinicaltrials.gov (identifier: NCT01794052)
- Clinical Trial Registry of India Number: CTRI/2013/02/003412

4.6 Description of the setting

Himachal Pradesh is a state in Northern India covering an area of 55,670 square kilometres, bordered by Jammu and Kashmir on the north, the plains of Punjab on the west and south-west, Haryana and Uttrarkhand on the south-east and by China on the east. The terrain of Himachal Pradesh is mountainous with elevation ranging from 450 metres to 6500 metres above sea level (Figure 4.5). The climatic conditions of Himachal Pradesh vary from hot and sub-humid tropical climate in the southern regions to very cold climate in the northern and eastern mountain ranges. Broadly, the state experiences three seasons: hot weather season, cold weather season and rainy season [163]. Himachal Pradesh is the least urbanised state in India, with nearly 92.5% of the population living in rural areas [163]. The economy of

Himachal Pradesh is fast-growing and is highly dependent on three sources: Hydroelectric power; Tourism; and Agriculture.

Demography and development indicators

According to provisional results of the Census of 2011, Himachal Pradesh has a total population of 6,856,509, including 3,473,892 males and 3,382,617 females, which constitutes 0.57% of India's total population [164]. The state has a high literacy level of 83.8% [164] and performs well in most development indicators, such as crude birth rate (16.5 versus national average 21.8), crude death rate (6.7 versus national average 7.1) and infant mortality rate (38 versus national average 44) [165].

Figure 4.5: Political map of Himachal Pradesh

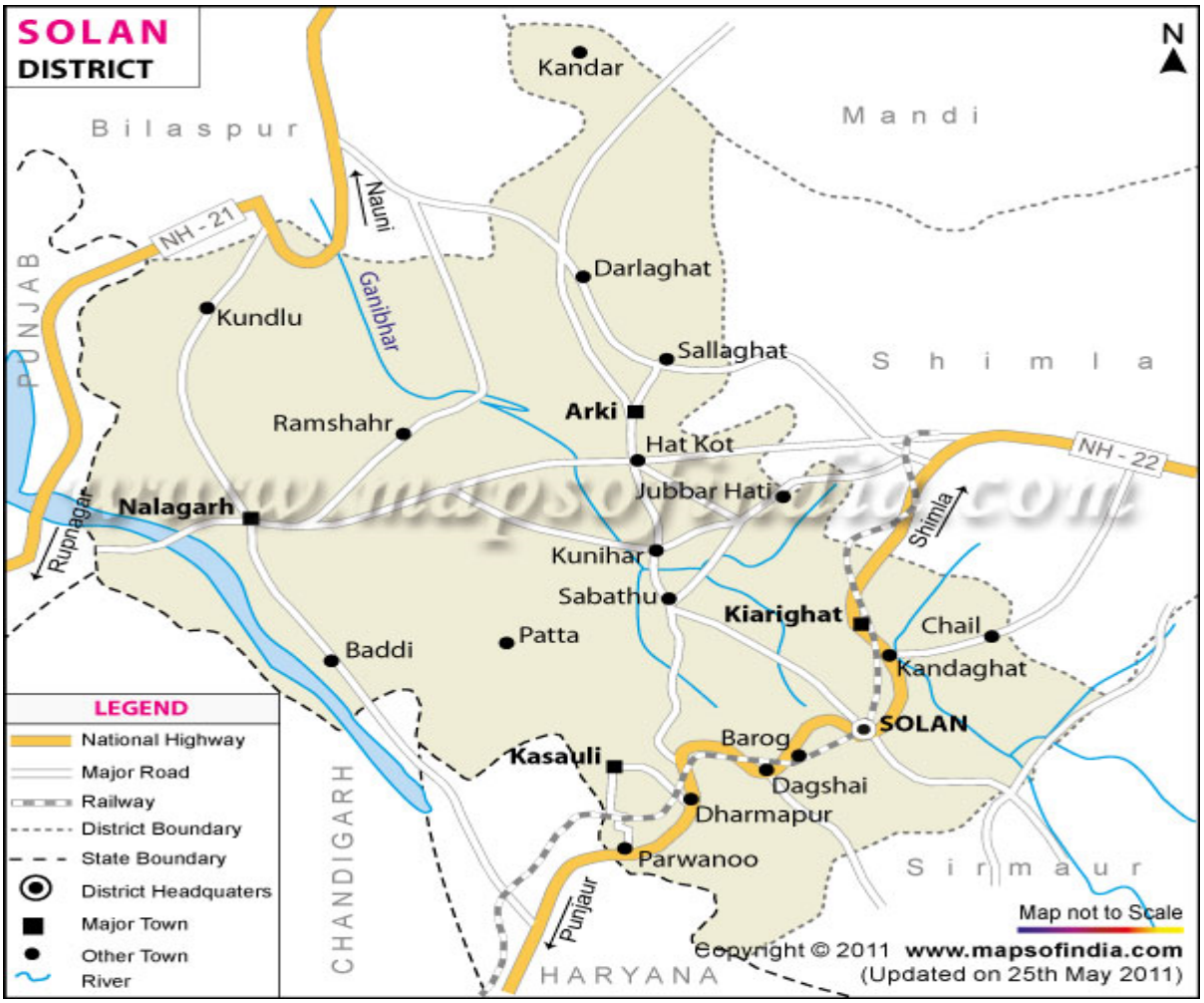
4.6.1 Description of Solan District, Himachal Pradesh

Himachal Pradesh is divided into 12 districts (an administrative geographical unit), namely: Shimla, Solan, Una, Bilaspur, Hamipur, Chamba, Lahul and Spiti, Kinnaur, Kullu, Sirmour

and Mandi (Figure 4.6). Solan district, which is spread over an area of 1936 square kilometres, has its district headquarters at Solan city, which is located 46 kilometres south of the state capital, Shimla. Solan is named after the Hindu goddess, Shoolini Devi, and is known as the "Mushroom city of India" because of the extensive mushroom farming in the district.

According to the 2011 census, Solan had a population of 580,320, of which males and females were 308,754 and 271,566, respectively, with a population density of 300 per square kilometres [164]. The overall literacy rate of the district in 2011 was 83.7 and the literacy rates among males (90.8%) were higher than those among females (76.6%).

Figure 4.6: Political map of Solan District



Source: www.mapsofindia.com

4.6.2 Healthcare infrastructure of Himachal Pradesh

The public sector plays a dominant role in the healthcare delivery in Himachal Pradesh. According to the most recent National Health Accounts Statistics available, Himachal Pradesh had the highest public sector expenditure (41.7%) as a proportion of total health spending during 2004-05, compared to 10 other major states in India, where it varied between 10 - 19%. [166]. The public sector is the sole provider of primary care services, while the role of the private sector is limited to curative care.

The public health system is run by the State Department of Health and Family Welfare, which is headed by the State Health Minister, with a Secretariat under the charge of Principal Secretary (Health and Family Welfare). The State Directorate of Health Services is the technical wing, headed by a Director of Health Services. The Director of the Health Services is responsible for the delivery of healthcare services through the public health system. The state health system is further divided into a district health system, which acts as a link between the State level and the periphery. The district officer with overall control is designated as the Chief Medical Officer (CMO), and is responsible for implementing the health programmes according to policies laid down and finalised at higher levels, i.e. State and Centre. The CMO is assisted by a District Health Officer.

Each district is further divided into blocks, having a population of 100,000 - 120,000 population. The Community Health Centre (CHC), headed by a Block Medical Officer (BMO), functions as a secondary care facility for each of the blocks. Further, there will be three to four Primary Health Centres under each CHC, providing primary care services to the community. An organogram of the Health Department of Himachal Pradesh is shown in Figure 4.7.

Figure 4.7: Organogram of Department of Health and Family Welfare – Himachal Pradesh, India

4.6.3 Healthcare organisation at district level

The healthcare organisation at the district level follows a three-tier pattern, with medical college hospitals providing tertiary care while district hospitals and CHCs serve as secondary care institutions.

The District/Regional Hospital provides comprehensive secondary healthcare services to the population in the district. As the population of a district is variable, the bed strength also varies from 75 to 500 beds, depending on the size, terrain and population of the district. It

also functions as a secondary level referral centre for health institutions below the district level, such as Community Health Centres, Primary Health Centres and sub-centres.

Community Health Centres (CHCs) constitute the secondary level of healthcare, catering to nearly 100,000-120,000 rural population of a block. CHCs deliver both Out-patient Department (OPD) and In-patient Department (IPD) services. The Indian Public Health Standards insists that CHCs run specialist clinics in general medicine, general surgery, dentistry, obstetrics and gynaecology, paediatrics and family welfare, with at least one specialist doctor from each of the respective disciplines. In addition, all the National Health Programmes are delivered through the CHCs.

Primary Health Centres (PHCs) are the cornerstone of rural health services - a first port of call to a qualified doctor of the public sector in rural areas covering nearly 30,000 population. PHCs often have only one Medical Officer, mostly non-specialists, act as referral unit for six sub-centres, and refers cases to CHC and higher order public hospitals located at sub-district and district level.

A sub-centre is a grass-roots level institution, catering to nearly 5,000 population (3000 in difficult terrain) and is manned by multipurpose health workers. A sub-centre provides an interface with the community, providing all the primary healthcare services. The health workers at the sub-centres routinely conduct field visits and provide out-reach care at the community level. Since sub-centres are the first contact point with the community, the success of any national health programme would depend largely on well-functioning sub-centres providing services of an acceptable standard to the people. [162]. The details of the healthcare infrastructure of Himachal Pradesh is shown in Table 4.4.

Table 4.4: Public health care infrastructure in Himachal Pradesh during 2005-2010

Type of health facility	Number
Sub Centres	2071
Primary Health Centres	449
Community Health Centre	73
District Hospitals	12
Medical Colleges	2
Dental Colleges	5

4.6.3.1 Health system of Solan District

The district health system of Solan is headed by a Chief Medical Officer. Solan has a Regional Hospital at the district level, offering secondary care and referral care. It has both in-patient and out-patient care departments. At sub-district level, there are five Community Health Centres headed by the Block Medical Officer. A more detailed description of the health facilities of the Solan district is provided under healthcare facility assessment in the results section.

4.6.4 Non-communicable disease (NCD) prevention and control programmes in the state

NCD control programmes in India are very recent. The National Program for the Prevention and Control of Cancer, Diabetes, Cardiovascular diseases and Stroke (NPCDCS), launched in 2008, is in a pilot mode, covering only 100 out of 640 districts in India. Initiated in 1011, the programme is currently operational in three districts of Himachal Pradesh, namely Chamba, Kinnaur and Lahul Spiti. The programme proposes to establish an NCD clinic at the level of CHCs and District Hospitals. The health services intended to be delivered from the NCD clinics are:

1. Prevention and health promotion activities, including counselling

2. Early diagnosis through clinical and laboratory investigations (blood sugar, lipid profile, ECG, ultrasound, X-ray.)

3. Management of common cardiovascular diseases, diabetes and stroke cases (both out-patients and in-patients)

4. Home-based care for bedridden chronic cases

5. Opportunistic screening for hypertension and diabetes at the OPDs

In addition to the above-listed activities, the NCD clinic at the district hospitals are expected to offer additional services, such as: advanced diagnostic services, intensive medical management of acute cases and act as referral centres for CHC level NCD clinics. The sub-centres are expect to conduct health education and screening for NCDs at the community level.

The following activities have been conducted as part of the programme since its launch in Himachal Pradesh:

- One Nodal Officer for Chamba district was trained at Indira Gandhi Medical College, Shimla, for implementing the programme

- A modern, fully-equipped six-bed Cardiac Care Unit was established in Chamba district

- 10 Awareness camps were organised in Chamba district.

- Organised hypertension and diabetes screening camps covering 259439 people, of whom 10075 had hypertension and 9046 had diabetes.

- Ninety-five paramedical staff were trained: 45 in Chamba and 50 in Kinnaur.

- A six days training given to three nurses in Indira Gandhi Medical College, Shimla

4.7 Fieldwork and my role in the study

I was the Project Coordinator and part of the Steering Committee of the mPower Heart Project, in which this PhD work was nested. I wrote the grant proposal to the Medtronic Foundation for the mPower Heart Project and a research proposal to the Public Health Foundation of India for funding my PhD work. I played a lead role in developing the study protocol, data collection and analysis of the data. I conducted the literature review and designed the intervention. I designed the overall evaluation, including all of the work presented in this thesis. I designed all elements of the in-depth interview tools. I contributed to the contents of the training manual for the Medical Officers and Nurse Care Coordinators and was part of the training team. I developed the logic for developing the software codes for the decision-support software. I coordinated the field work, starting from interacting with the health functionaries during planning and implementing the pilot in all the health facilities. I conducted the in-depth interviews during baseline health facility assessment and post-intervention evaluation. I conducted all analyses and interpreted the findings of the analyses.

I have written three papers deriving inputs from the literature review of this PhD work. The first paper describes the scope of Smartphone technology in diabetes interventions, while the second paper reviews the scope of Smartphone technology in tobacco cessation interventions. The third paper delineates themes of clinical research to strengthen the healthcare organisation in India to deliver high quality cardiovascular healthcare.

SECTION C

Outline of the section

In this section, results from the study are presented. This section is further divided into four chapters (Chapter 5, 6, 7, & 8). Chapter 5 describes the results from the design phase, which is sub-divided into two sub-sections. The first section narrates the steps followed for seeking approvals and support from the health authorities. The second sub-section describes the objectives, the detailed methodology of the needs assessment carried out at the health facilities, discusses the results and draws conclusions.

Chapter 6 elaborates the formation of a basic structure of the intervention package.

Chapter 7 narrates the evaluation of the adoption stage of the intervention at the health facilities.

Chapter 8 describes detailed methods for evaluation of the implementation and continuation stage of the intervention followed by discussing results from the evaluation.

Chapter 5: Results from the design phase

5.1 Steps followed for seeking approval/support from the health system for designing and implementing the intervention

In order to implement new projects, permission from the state government was essential. The Principal Investigators (Profs D Prabhakaran and Nikhil Tandon) of mPower Heart Project and the Study Coordinator (author of this thesis) visited the Health Secretary and made a formal presentation, seeking approval from the government for the designing and implementing of the project in the State.

In response to our request to the government, the Director of Health Services passed a written government order approving the implementation of the project and designated an Officer on Special Duty (OSD) to liaise between the project team's activities and the state health department. As per the advice of the State Government, Solan District was chosen for the project, considering its better road and mobile phone connectivity in comparison to other districts.

Subsequently, the Project Coordinator (the author of the thesis) attended a monthly meeting of the health department at the district headquarters, during which the Chief Medical Officer (CMO) introduced the project to the Block Medical Officers (BMOs) in order to ensure full support and cooperation from the health system.

In the meeting, the Project Coordinator apprised the BMOs about the project activities in detail and the plan to conduct a needs assessment exercise through a Health Facility Assessment (HFA) survey and in-depth interviews. With help from the CMO, HFA was scheduled for all the five Community Health Centres, in consultation with the BMOs. A Project Manager was appointed to carry out the day-to-day activities of the project.

Subsequent to HFA, the recruitment of study staff was conducted in consultation with CMO and the OSD.

5.2 Needs Assessment

Following approvals from the health system, a needs assessment exercise was conducted at the primary care facilities. Needs assessment was essential to understand the existing capacity and gaps in care at health facilities. Further, additional inputs were required from the healthcare team in designing training modules, developing tools for providing evidence-based care and tailoring the intervention adaptable to local context.

5.2.1 Objectives of the needs assessment exercise

1. To conduct a health facility assessment of the Community Health Centres and sub-centres to derive inputs to design an intervention for hypertension and diabetes care at primary care settings in Himachal Pradesh, India
2. To explore the perspectives of the healthcare team, with regard to providing hypertension and diabetes care from Community Health Centres, in order to derive inputs to design an intervention for hypertension and diabetes care at primary care setting in Himachal Pradesh, India

5.2.2 Detailed Methodology

Mixed methods (described in below sections) were used for conducting the health facility assessment, which included a tool-based Health Facility Assessment (HFA) survey, which was quantitative in nature, and 2) in-depth interviews with the healthcare team.

5.2.2.1 Quantitative methods

Needs assessment was carried out at the selected health facilities through a Health Facility Assessment (HFA) survey using a tool developed from the *Indian Public Health Standards (IPHS)* which is a set of uniform standards used as the reference point for public health care

infrastructure planning in India. *IPHS for Community Health Centres* prescribes various standards to provide optimal specialised care to the community and achieve and maintain an acceptable standard of quality of care at Community Health Centres [162]. IPHS recommends standards for service delivery for each of the ongoing national health programmes - which broadly fall under communicable, non-communicable diseases and maternal and child health – and the required manpower, laboratory/diagnostic equipment and drug supply for each of the programmes. The HFA tool developed thus covered the entire four domains (i.e. Service Delivery, Manpower, Equipment and Drugs) in relation to provision of hypertension and diabetes care from CHCs. The HFA survey was conducted in all the five CHCs by myself along with a physician trained in community medicine. In addition, secondary data from the registers and records maintained at the CHC were also collected.

Selection of the health facilities

All the five Community Health Centres of Solan District were included in the HFA survey. For the HFA survey, a total of 10 sub-centres were surveyed. For this, two sub-centres were randomly chosen from a list of six sub-centres that fell in the catchment area of the CHCs within a radius of five kilometres. Thus, the sample covered one third of the 30 sub-centres to which the CHCs directly caters for care provision.

Data Analysis

The data collected from the HFA survey was tabulated and compared with the prescribed IPHS standards for CHCs in order to assess the capacity of the individual CHCs to provide hypertension/diabetes care on a par with the recommended standards.

5.2.2.2 Qualitative methods

In addition to HFA, in-depth interviews (IDIs) with various stakeholders in the healthcare organisation were carried out. Further, observations of the functioning of the CHCs and assessment of the records of the health facility were also made. The themes for the IDIs were based on the objectives of the study. Different themes were developed for different categories of the healthcare team. **Broadly speaking, themes were constructed around perceptions of the healthcare team on 1) nature of the current services; 2) facilitators and barriers to hypertension/diabetes care; 3) potential factors that could influence a new intervention; 4) perceived appropriateness of introducing a new intervention within the work culture of the organisation; and 5) additional skill and training required for hypertension/diabetes care in their respective work domain**.

Sampling

The qualitative study used purposive sampling to select the interviewees to ensure that perspectives of individuals with varied roles in the healthcare organisation were assessed. Within the healthcare organisation, stakeholders included two District Health Administrators (there were only two district level functionaries in Solan), three Block Medical Officers (Head of the Community Health Centres) of five CHCs, five Medical Officers of the CHCs, five nurses and 15 health workers. The number of participants for each of the above group was decided using saturation principle, i.e. continued till no new information was obtained from the interviews. Further, non-participant observation was made at the CHCs to understand the work flow, availability of facilities and workload of the staff. The interview guides for each group are appended (Appendix-3)

Conduct of the interviews

Each potential interviewee was contacted by myself and invited for an interview at a time convenient to them. The interviews with the Health Administrators and Medical Officers were conducted by myself, while interviews with other staff cadre (nurses and health workers) were conducted by three research staff whom I trained using the interview guide, as well as through mock interviews. The interviews were conducted in settings ensuring sufficient privacy and confidentiality after providing a brief description of the study and obtaining a signed informed consent of the participant. The interviews were conducted in Hindi or English and were digitally recorded. The interview notes and recordings were reviewed on the same day and themes and questions were further developed using an inductive approach. This approach enriched the data collection procedure, allowing for flexibility in themes.

Data Analysis

The thematic content analysis approach was used to explore the data so that thick, rich descriptions could be identified to exemplify the multiple perspectives and realities of the sample for examining the specific themes explored in the in-depth interviews and deriving meaningful insights and interpretations [167]. Coding rules were established, including exhaustive coding, allowance for double-coding when appropriate and coding passages at the smallest level of meaning, using the qualitative research analysis software, NVIVO 10. The specific analytic functions for which NVIVO was used were: 1) establishing the coding structure elements in an NVIVO analysis file; 2) coding each piece of in-depth interview transcripts and sorting; and 3) searching within the coded data. One coder (AVS) openly coded all transcripts to create definitions and codebook. Memos were taken during this process. Each individual code was reviewed in full to assure proper placement of relevant

text. Saturation was documented, following the first round of open coding. Following this, a draft codebook was created. One more coder (AAS) was trained in these definitions and engaged in AXIAL coding, whereby the coder applied these codes to the transcriptions. Our team reviewed codes to identify areas where they conceptually overlapped or could be brought together to form higher order themes. These themes were organised and described with the conceptual framework to narrate the results. In order to preserve anonymity in the use of quotes, the participants were given a tag combining their age, gender and designation. Their specific role was not distinguished, as this would lead to the possibility of identifying a specific person.

5.2.3 Results

5.2.3.1 Results from the Health Facility Assessment conducted at five CHCs

The health facility assessment was carried out in five Solan community health centres, namely: CHC Dharampur, CHC Dharlagarh, CHC Syri, CHC Kunihar and CHC Nalagarh. The results of HFA with regard to service delivery, manpower, equipment and drugs are described below.

Service Delivery

Results from assessment of three elements of service delivery pertaining to IPHS standards were:

1) *Treatment and timely referral (of complicated cases) of diabetes and hypertension* were available from the Out-patient Departments (OPDs) of all the five CHCs. In-patient care of hypertension emergencies were done at CHC Nalagarh and Kunihar only. Complicated cases of diabetes and hypertension were usually referred to Indira Gandhi Medical College (IGMC), Shimla, or the Post-graduate Institute, Chandigarh, for treatment. Patient referral was at the discretion of physicians as there were no specific guidelines on

referral. None of the facilities were doing active follow-up of patients for compliance to medicines or follow-up visits.

2) *Health promotion activities pertaining to prevention and control of diabetes and hypertension* recommended by the IPHS for CHCs were promotion of healthy dietary habits, physical activity, avoidance of tobacco and alcohol and stress management. Excluding the advice given to patients by the Medical Officers in the very limited time available at the OPDs, none of these health promotion activities for diabetes or hypertension were carried out by any of the CHCs, either at the OPDs or at the community level.
3) *Early detection (screening and diagnosis of HTN and DM)* through opportunistic screening was not part of the routine care at the OPDs

Comparison of service delivery from the CHCs in relation to the IPHS standards is depicted in Table 5.1.

Table 5.1: Service delivery from the CHCs in comparison with IPHS

Services	CHC Dharampur	CHC Dharlagarh	CHC Syri	CHC Kunihar*	CHC Nalagarh**
Treatment & timely referral (Complicated cases) of diabetes and hypertension (Outpatient care)	Yes	Yes	Yes	Yes	Yes
Health promotion activities pertaining to prevention and control of hypertension and diabetes	No	No	No	No	No
Early detection (Screening and diagnosis of hypertension and diabetes)	No	No	No	No	No
In-patient care for Acute/ emergency of hypertension and diabetes	No	No	No	Yes	Yes

*CHC Kunihar had three general duty doctors and better inpatient facilities

**CHC Nalagarh has the status of a First Referral Unit and has a 100 bedded in-patient unit

Drug Supply

The IPHS recommends a list of essential medicines to be available at CHCs for free distribution to patients attending the OPD. These include anti-hypertensive medications, oral-hypoglycaemic agents and insulin that the health department is to supply the CHCs. The anti-hypertensive medications included in the list were Atenolol, Metoprolol, Amlodipine, Enalapril, Captopril and Hydrochlorthiazide. At the time of the HFA survey, all the five CHCs had Atenolol and Amlodipine in stock. Enalapril (ACE-Inhibitor) was not available in one of the CHCs, while Metoprolol, Captopril and Hydrochlorthiazide were not available at any of the CHCs (see Table – 5.2).

Oral-hypoglycaemic agents recommended in IPHS were Metformin and Glibenclamide, of which only Metformin was available at all the CHCs. Instead of Glibenclamide, Glipizide was available in four of the five CHCs. Although recommended in IPHS, none of the facilities had insulin in stock. The availability of some of the related medications used in cardiovascular disease management (and included in the IPHS list) was also assessed, such as Aspirin (available in three CHCs), Atorvastatin (available in one CHC) and Streptokinase (not available at any of the CHCs).

Table 5.2: Drug availability at the CHCs in comparison with IPHS

Drugs	CHC Dharampur	CHC Dharlagarh	CHC Syri	CHC Kunihar	CHC Nalagarh
Tab Atenolol	Yes	Yes	Yes	Yes	Yes
Tab Metoprolol	No	No	No	No	No
Tab Amlodipine	Yes	Yes	Yes	Yes	Yes
Tab Captopril	No	No	No	No	No
Tab Enalapril	Yes	Yes	No	Yes	Yes
Tab Hydrochlorthiazide	No	No	No	No	No
Tab Metformin	Yes	Yes	Yes	Yes	Yes
Tab Glipizide	Yes	No	Yes	Yes	Yes
Tab Glibenclamide	No	No	No	No	No
Inj Insulin	No	No	No	No	Yes
Tab Atrovastatin	No	No	No	No	Yes
Tab Aspirin	Yes	Yes	No	Yes	No
Inj Streptokinase	No	No	No	No	No

Equipment

The availability of IPHS-recommended equipment for diabetes and hypertension care was as follows: all the CHCs had a mercury sphygmomanometer (Mercury type) and stethoscope while an ECG machine was available only in three CHCs. An Ophthalmoscope for the detection of retinopathy was available only at CHC Nalagarh, which had an ophthalmologist posted (see Table 5.3).

Table 5.3: Equipment availability at the CHCs in comparison with IPHS

Equipment	CHC Dharampur	CHC Dharlagarh	CHC Syri	CHC Kunihar	CHC Nalagarh
ECG Machine	Yes	No	No	Yes	Yes
BP Apparatus	Yes	Yes	Yes	Yes	Yes
Stethoscope	Yes	Yes	Yes	Yes	Yes
Opthalmoscope	No	No	No	No	Yes

Laboratory Services

The IPHS recommendation included provision of laboratory services for blood sugar, blood cholesterol, lipid profile, kidney function test (blood urea/creatinine), liver function test, ECG, urine albumin and urine sugar estimations. All the CHCs had lab facilities for blood sugar investigation, while total cholesterol and lipid profile investigations were available at two of the five CHCs. Investigations such as liver function test and kidney function test were carried out in only two CHCs. Urine albumin and urine sugar estimations were available from all the CHCs (see Table 5.4).

Table 5.4: Laboratory services at the CHCs in comparison with IPHS

Laboratory Services	CHC Dharampur	CHC Dharlagarh	CHC Syri	CHC Kunihar	CHC Nalagarh
Blood Sugar	Yes	Yes	Yes	Yes	Yes
Blood Cholesterol	Yes	No	No	Yes	No
Lipid Profile	Yes	No	No	Yes	No
Kidney Function Test (Blood Urea/creatinine)	Yes	Yes	Yes	Yes	No
Liver Function Test	Yes	Yes	No	Yes	No
ECG	Yes	No	No	Yes	Yes
Urine Albumin	Yes	Yes	Yes	Yes	Yes
Urine Sugar	Yes	Yes	Yes	Yes	Yes

Manpower

The IPHS recommends one general medicine specialist at the CHCs. However, only two of the five CHCs had a specialist in general medicine posted. As against the six general duty Medical Officers (MBBS) recommended, CHCs Dharampur and Kunihar had three and four, respectively, including the Block Medical Officer; CHCs Nalagarh and Syri had three each (including Block Medical Officer) while CHC Dharlagarh had only one general duty Medical Officer, who was in charge of BMO. However, CHC Nalagarh additionally had seven specialists in various other disciplines posted. There was a shortage of lab technician cadre to meet the recommended three positions in each CHC; however, it was partially addressed by rotating two lab technicians in four of the CHCs, with fixed day assignments to each CHC each week. On an average, a lab technician would be available two to three days a week at a CHC. None of the CHCs had an ECG technician at the time of HFA. The shortage of staff was highest in the nurse cadre. Although 15 nurse positions were recommended as essential for each CHC, three of the CHCs had only two nurses or less, while one of the CHC had five nurses. CHC Nalagarh, because of its additional status as a First Referral Unit (FRU) with a 100 bedded in-patient unit, had 26 nurses. All the nurses were posted for the in-patient care unit and none of them were available at the out-patient department (see Table 5.5).

Table 5.5: Manpower available at the CHCs in comparison with IPHS

Manpower	Recommended by IPHS	CHC Dharampur	CHC Dharlagarh	CHC Syri	CHC Kunihar	CHC Nalagarh
Block Medical Officer	1	1	No	1	1	1
Specialist physician in General Medicine	1	No	No	No	1	1
General duty medical officers (MBBS)	6	2	1	2	3	2
Lab-Technician	3	Yes	Yes	Yes	Yes	No
ECG technician	1	No	No	No	No	No
Nurse	15	2	1	2	5	26

Additional Observations

The opening time of the out-patient department (OPD) of the CHCs was from 9:30am to 4pm, with a one-hour lunch break, from Monday to Saturday. The number of patients attending these OPDs varied greatly. While CHC Syri had a lower OPD strength (40 patients a day), CHC Nalagarh was serving an average of 450 patients in a day. There were no special clinics for diabetes or hypertension care. The Medical Officer attending the OPDs provided care to such patients. Although the Government of India had issued a clinical management guideline for diabetes/hypertension at primary care facilities, none of these CHCs were supplied with print copies of the guidelines.

5.2.3.2 Results from the health facility assessment conducted at sub-centres:

The results of the HFA survey carried out in 10 sub-centres were as follows. The sub-centres were manned by a single female health worker, except in two sub-centres which had an additional male health worker. Although provision of information education and

communication (IEC) on hypertension and diabetes was part of the recommended service delivery from the sub-centre, in-service training was not provided to the health workers in delivering such services to the community. Similarly, although IPHS included estimation of urine sugar and proteins using dipstick method, none of the sub-centres had such provisions because of lack of supplies.

The IPHS does not recommend provision of any of the anti-hypertensive/anti-diabetic medications and, hence, drug supply did not include any such medicines. Basic equipment, such as sphygmomanometer, stethoscope, weighing scale, height measuring scale (marking made on the walls) and disposable lancets were available in most of the sub-centres. However three out of ten of the sub-centres did not have a stethoscope, while one of the sub-centres did not have a sphygmomanometer.

5.2.3.3 Results from qualitative research (in-depth interviews)

In-depth interviews (IDIs) were conducted with healthcare teams at the CHCs in order to derive feedback for designing the intervention. A total of 30 in-depth interviews were conducted with Health Administrators (2), Block Medical Officers (3), Medical Officers (5), nurses (5) and health workers (15) until data saturation was reached. The IDIs were conducted to explore the current status of hypertension/diabetes care at CHCs, barriers to care, opinions on initiating a new intervention for diabetes and hypertension at CHCs and inputs for developing supporting measures such as training needs, manpower, etc.

The narratives of the healthcare team revealed that hypertension and diabetes have become important health problems, because of an increase in the number of such cases they come across at the CHC. The healthcare team, particularly the Medical Officers, were of the opinion that the younger groups were becoming vulnerable to these diseases and the health

department needed to consider new initiatives to tackle non-communicable diseases as a whole. The key themes emerged from the interviews are described below:

The healthcare team, particularly the Medical Officers, narrated several barriers they faced in providing care to hypertension and diabetes patients. The major barriers cited by the Block Medical Officers, Medical Officers and the Health Administrators were:

- ***Heavy patient load at the OPDs:*** all the Medical Officers were of the opinion that heavy patient load at the OPDs precluded them from conducting thorough patient evaluation and behaviour change counselling. The number of patients attending OPD ranged from 100-200 in all the CHCs except CHC Syri, where the OPD strength was 40-50 a day. The heavy workload resulting from shortage of manpower in the health system was a major concern. A specialist physician stated:

  "You have seen the workload and the number of patients we have. In a normal day, I see around 20-25 ECGs and 40-50 X- rays at my OPD. We don't have enough doctors to manage this crowd. How can you expect a single person to handle this entire workload? I can only spend one or two minutes with a patient and beyond that it would be a luxury in this condition."

  Further, a medical officer said:

  "We have a shortage of staff here. I recommend that there should be one or two additional doctors and nurses for attending patients at the OPD."

  Another Medical Officer reported:

  "Ideally, we should be spending at least 10 minutes, but I don't get that much time for advising patients on diet or lifestyle. I explain to them only about taking medicines".

- ***Insufficient supply of drugs:*** all the doctors interviewed pointed out that insufficient supply of medicine for patients attending OPDs was affecting compliance, due to the fact that the medications used in chronic care need to be taken lifelong and are expensive. The medicine supply at the government facilities was erratic and, hence, patients were given prescriptions to purchase medicines from private vendors, which added to cost of care to the patients. A Medical Officer said:

  "This is the main problem with government hospitals; we don't have enough supply of medicines regularly. If the medicines are supplied in good quality and quantity, then we could treat the patients in a much better way"

- ***Unavailability of diagnostic facilities:*** the Medical Officers were of the opinion that lack of basic diagnostic services to conduct investigations, such as ECGs, glucometers, blood glucose and renal function tests, are causing difficulty for patients, as they need to rely on private laboratories. Due to this reason, patients prefer to go to higher centres, such as Indira Gandhi Medical College, Shimla or Post-Graduate Institute at Chandigarh, which are tertiary care facilities with adequate facilities and specialist physicians for care. A Block Medical Officer stated:

  "We have an ECG machine, but it is idling because we don't have an ECG technician. For diabetes patients, it would have been much useful if we get glucometers and strips; but we never had glucometer supplied to us. In a busy OPD, glucometer would be ideal as it gives quick results and makes our job easy and it will save a lot of time for the patients as well. Such facilities must be made available here".

According to another Medical Officer:

"Our lab is dysfunctional. We don't have a lab technician for the last four years. So it is very difficult for us to manage patients, not only diabetes or hypertension patients, but other patients as well".

- ***Lack of specialist positions at CHCs:*** only two out of five CHCs had a specialist physician available. The basic Medical Officers were reluctant to treat complicated cases of hypertension and diabetes patients on insulin, due to lack of training. This fact was evident while interviewing Medical Officers with basic qualifications as well as from the responses from the Health Administrators. A District Health Administrator said:

  "Insulin supply is part of the reproductive and child health (RCH) supplies from NRHM. We are ready to provide this to CHCs, but basic Medical Officers with only MBBS qualification are not using it, because they are not comfortable in using it. They think that specialists should be prescribing insulin".

  A Medical Officer reported:

  "I don't prefer treating hypertension and diabetic patients; I usually refer them to the MDs (specialist physicians), but if they are not available, then I treat them. I advise patients about the need for lifestyle changes, type of diet they need to have and prescribe medicines".

- ***Insufficient use of clinical management guidelines:*** the IDIs revealed that clinical management guidelines were not followed for managing hypertension and diabetes in any of the CHCs. It was found that the Health Department had not circulated the clinical

management guidelines published by the Government of India for managing hypertension/diabetes at primary care level to any of these facilities. None of the Medical Officers were aware of any such guidelines issued by the government. When further explored for their opinion on whether they would welcome such a guideline, the Medical Officers were very much in favour of following a guideline issued by the government.

A Medical Officer stated:

"We don't have a clinical management guideline issued to us from the department. I wish we have one for our use, but, along with such guidelines, we would also need regular supply of drugs, glucometers and facilities to run fasting glucose, LFT, KFT at our lab. And there has to be lab technicians posted here".

- ***Training requirement:*** the need for refresher training (Continued Medical Education) emerged as a strong requirement from the narratives of the Medical Officers. After joining the health services, none of the doctors received any training on managing hypertension or diabetes. This limits the Medical Officers' exposure to new developments in medical care and adopting appropriate changes in practices. Five major training needs that emerged from the in-depth interviews were:
  1) current diagnostic criteria of hypertension/diabetes;
  2) clinical management of patients with/without complications;
  3) drugs and their indications, side effects, drug interactions and contra-indications;
  4) using clinical management guidelines; and
  5) therapeutic lifestyle change advice, including diet.

A Medical Officer made the following opinion on training needs on NCDs:

"I think training on management of NCDs is required for all Medical Officers. Nowadays, we are getting lot of hypertension and diabetes patients. So if we don't have enough knowledge to treat and educate such patients, then it becomes very difficult. So the staff, or at least the Medical Officers, have to be trained."

5.2.3.4 Role of nurses in hypertension/diabetes as perceived by nurses

In-depth interviews were conducted with five nurses to explore their perspectives on their potential roles in hypertension and diabetes at CHCs. The narrations from the nurses revealed that nurses did not see any role for themselves at the OPD in conducting patient evaluation or advising patients on drugs or lifestyle changes. The nurses viewed that their role was limited to indoor functions, such as care of in-patients admitted in wards. These notions stemmed from the traditional roles of nurses in health systems and the training they received. However, nurses explained that they do advise patients on lifestyle changes and the importance of compliance to medications to hypertension/diabetes patients admitted in wards.

A nurse made the following observation:

"I have never done patient examination at the OPD so far. Our duty is to attend patients who are admitted in the wards. Here we get diabetes patients admitted and doctors prescribe them medicines and we can only provide them nursing care, like giving insulin injection, glucometer readings, dressing foot ulcers. All these are done under doctor's supervision. We also provide health education to patients"

5.2.3.5 Opinions of the healthcare team about initiating an intervention for diabetes/ hypertension at CHCs

In general, the Health Administrators and Medical Officers welcomed the proposed intervention for hypertension and diabetes patients, describing it as 'very important' or 'useful' to the community. However, the Medical Officers were sceptical about following a detailed patient evaluation plan with the use of a clinical management guideline when it was described to them in detail. The main concern was lack of time due to heavy workload. Although Medical Officers agreed that the intervention was going to improve the quality of care with the use of a Smartphone-based clinical decision-support tool, they immediately rejected the idea of them using Smartphone software. The reason cited was that patient evaluation using a Smartphone based tool would overburden their already heavy workload.

A Medical Officer said:

"I think it will be very tough to do so. Because in CHC we have more than 200 patients in a day; so for doctors, it will be very difficult to use this Smartphone."

Another Medical Officer said:

"I think this is a good programme and the patients will benefit. But as I understand, workload will increase substantially as you are not going to provide any additional doctor."

According to a specialist physician:

"If you provide staff, then we can implement this project; otherwise it is not possible because we already have shortage of staff."

When further exploring a way of addressing the workload issue, the doctors suggested that a dedicated person at the OPD who could facilitate care by helping the doctors could be a

solution. We then proposed a choice between appointing either a health worker or a nurse at the OPD, assigning them duties such as opportunistic screening and conducting history-taking / initial patient evaluation using a software tool. All the doctors were of the opinion that a nurse would be best suited for such a work.

A specialist physician stated:

"A nurse at the OPD would be extremely helpful for us. She can counsel patients and also help the doctors."

A Health Administrator had the following opinion about the choice of nurses:

"I think nurses will be more suitable and efficient for this work, because they have higher qualifications, experience and knowledge than health workers. They study three and half years and their curriculum is better, they could handle technology in a much better way."

5.2.3.6 Training needs as felt by the nurses

During IDIs, the nurses were asked to suggest what additional training would be required for a nurse posted at the OPD to manage hypertension/diabetes patients. The topics identified by the nurses for additional training were:

1) the cause of hypertension/diabetes;
2) indications and doses of various diabetes/hypertension medications;
3) training on advising and motivating patients on diet and physical activity;
4) using electronic blood pressure monitors and glucometers;
5) conducting history-taking and patient evaluation; and
6) managing emergency cases in the absence of doctors

These inputs were used to develop the training modules for the intervention. In relation to

training requirement a nurse said:

"it will be helpful for us if you could provide us training related to various medicine used for treating hypertension and diabetes, because, for such patients, when doctors prescribe medicines we need to educate the patients about using those medications."

Another nurse said:

"We should be able to manage emergency cases when the doctors are not available; in such situations, we should be able to provide some emergency care to them."

Another nurse stated:

"Nurses need to be trained to educate patients regarding diabetes and hypertension and convince them to change their behaviours. We want to learn how to interact with patients, diagnose the conditions using newer methods like automatic BP monitor, glucometers."

5.2.3.7 Perspectives of Health Workers

Health workers are the grass roots level workforce in primary healthcare. Each CHC had seven to eight sub-centres under their jurisdiction, manned by a health worker to mainly deliver maternal and child healthcare services (MCH) to the community. The IDIs with the health workers were conducted to identify whether there were potential roles for them in hypertension/diabetes care at the community level. Further, the suitability of health workers at OPDs in a facilitating role was also explored.

The IDIs explored the current nature of work of the health workers. Their work schedule follows a pre-planned monthly programme approved by the respective BMOs. In the morning session, the health workers stay at the sub-centre, running Maternal and Child Health (MCH) clinics. In the afternoon, they conduct field visits for family planning services, follow-up of pregnant mothers, distribution of iron and folic acid tablets and immunisation of children. A minimum of 16 field visits are to be made in a month. They also organize two to three clinic days in a month, during which doctors visit the sub-centre to treat patients.

All the health workers were of the opinion that they were experiencing a change in the demand for healthcare from the community regarding chronic disease care, which they were unable to provide or adequately answer questions / doubts from the community. The absence of any in-service training to attend to such demands from the community was reflected in their words. For example a female health worker said:

"We come across a lot of hypertension and diabetes patients at the community and we need to care for them as well. So I think we do have a role in it, but due to lack of training, we don't have enough knowledge to provide them any advice or drugs."

According to a male health worker:

"Our department needs to organise trainings for us on measuring blood pressure and doing sugar test, because we are not much trained in these tasks."

The narratives of the health workers revealed that the sub-centre facilities are inadequate to provide care for such patients. The health workers do not carry blood pressure monitors with

them during field visits and the only care they can provide to such patients is measuring blood pressure at the sub-centre and telling them whether it is under control. They also don't have glucometers to provide similar help to diabetes patients. Further, the drug supply at the sub-centre does not have anti-hypertensive or anti-diabetic medication for patients. A female health worker made the following observation:

"At sub-centres we give medicines to pregnant women and children. We don't give any medicines for a person with other diseases, which I think is not good. We don't have medicines for hypertension or diabetes patients. Nowadays, we come across many patients with hypertension or diabetes. We can measure blood pressure and tell them whether it is under control. But we don't have glucometer to check the diabetic patients; that's a drawback in our work."

We found that those health workers whose family members have had hypertension or diabetes had better knowledge about those conditions and were able to help in explaining to patients in a much better way. For example, a female health worker said:

"My mother has hypertension; that is the reason why I am very conscious about that; I educate people and give advice to such patients I come across during my field visit."

All the health workers we interviewed seemed to have realised that they had a role to play in the community for hypertension and diabetes care and, with additional training, were confident about assuming those roles. A female health worker stated:

"As a Health Worker, we have a big role to play because people came to us first and seek our advice before going to the doctors. So, if we are trained well we could guide them properly at that point of time and also help them on the medicine they receive from the hospital later."

5.2.3.8 Experience of health workers in using mobile phone technology as part of their duties

We explored the experience of health workers in using Smartphones and the Internet for activities related to their duties. The health workers were not new to using the Internet or mobile phones for such purposes. They were using an Internet-based reporting system for transferring consolidated monthly figures pertaining to maternal and child healthcare from their jurisdiction to the state authorities. A mobile-based reporting system subsequently replaced the desktop-based system and the health workers were very much impressed with the new system. A female health worker stated:

"In the last month, we had training on mobile- based reporting of our monthly reports to the headquarters. There are a total of three forms which we have to fill in. It has become easier for us because our paper work has become less."

We then explored the difficulties they were facing in using the new system and our proposal to use Smartphone software for the clinical staff. The response was encouraging. A female health worker said:

"Why not; it will helpful for us. But there could be some problems. Older staff will have difficulty in using mobiles. Sometimes we also make mistakes. So my opinion is that we need good training. At the beginning everyone will face some or other problem, but later things will improve, everything will settle down."

During the interviews, the health workers often cited their heavy workload in the field. The addition of a community outreach programme, comprising of screening for high risk subjects at the community level and linking them with the CHC and providing follow-up care, was

discussed with them. Most health workers were hesitant to add such a task to their current job responsibilities. However, they indicated that, in sub-centres where there are two health workers (a male and a female) posted, such a service could be initiated. However, the shortage of trained health workers in the government in the near future became evident from their narratives, risking the launch of a community outreach element through the health workers. According to a female health worker:

"We are overburdened with work. We have to manage MCH (maternal and child health), community planning, survey and communicable diseases. How can a single person manage all these work in a sub-centre? We need additional staff for this. Or else, you could start this programme in sub-centres, having two health workers. Nowadays, the government is not appointing any health workers and they have stopped the health worker training. Most health workers are going to retire in the next 10 years. So how will you run this programme?"

5.2.4 Discussion

The health facility assessment and needs assessment exercise carried out at five CHCs of Solan district, Himachal Pradesh, revealed the mismatch between demand for care and the capacity of the health system for the provision of hypertension and diabetes care. None of the five CHCs was fully meeting Indian Public Health Standards with regard to manpower, equipment, drugs and laboratory facilities to meet the recommended service delivery from a CHC [162]. Such inadequacies were expressed as a barrier to care by the members of the healthcare team such as physicians, nurses, health workers and the health administrators. Although hypertension and diabetes care was yet to be part of the routine primary care services through a national program, the members of various health cadre had already recognized the growing importance of these two diseases and cited the requirement of

additional training, need for clinical management guidelines and other support facilities for detecting and delivering optimal care for such patients.

Among various barriers identified shortage of manpower - particularly specialist physicians, nurses and lab technicians - was the major challenge to planning new interventions. The shortfall in numbers was consistent with state statistics: specialist physicians (97%), nurses (63%), lab technicians (64%) as of March 2012 [168]. This was further complicated by heavy patient load at the OPDs which put pressure on medical officers to quickly dispose of patients without conducting detailed patient evaluation. Hence, while planning new interventions, such constraints need be considered before introducing them in an Indian setting. Therefore, provision of additional manpower along with exploring possibilities of task-shifting or task-sharing is essential to carry out additional work related to screening and use of a new clinical management guideline which requires healthcare professionals to spend more time with the patients. It was a major finding that doctors may not be in a position to use a smartphone-based decision support tools or any other such tools because of time constraints in busy out-patient clinics. This finding reiterates the importance of additional manpower required for new interventions in most CHCs in India. Given these facts, the findings from the systematic reviews elaborated in Chapter Three supports that nurses could play a major role in hypertension/diabetes care intervention. A Cochrane review that compared nurses and physicians in primary healthcare services provision, has also reported similar health outcomes for patients, process of care, and resource utilisation or cost between the groups [76]. The feasibility and utility of nurse-led hypertension and diabetes management at primary care has been demonstrated in developing world such as Sub-Saharan Africa [77, 78]. Such task-shifting attempts could be a solution for addressing manpower shortage particularly high cost manpower such as physicians. However, there are challenges to such task-shifting efforts. Traditionally, in India, nurses are assigned only for indoor functions such as caring of

patients in the in-patient wards. Conducting screening and patient evaluation at out-patient departments was never been part of job responsibilities of nurses. In addition, nurses, even after post-graduate qualifications, are not permitted to prescribe medicines as the concept of Nurse Care Practitioners is not legally recognised in India. In such circumstances adding new roles to job function of nurses will be challenging. During the in-depth interviews, none of the nurses could give a clear opinion on potentially newer job functions such as patient evaluation in out-patient departments. Such unconventional roles require support from their superior staff, most importantly doctors, and interventions needs to be carefully planned to ensure such support.

The growing demand for hypertension and diabetes care at the community level was increasingly felt by the healthcare team at the CHCs. Lack of training to respond to such needs from the community was echoed by doctors, nurse and health workers. Lack of training, together with, absence of standard clinical management guidelines has resulted in variations in patient assessment and management across health facilities. In this scenario, imparting additional knowledge and skills through training and providing decision support tools to the health care team are essential to standardize care across facilities. Involvement of physicians in task-shifting/ task-sharing with nurses is also equally important. To play supervisory roles in clinic setting, physicians need to be clear about the approach of nurses with patients in different clinical scenarios.

Though there is no convincing evidence from both developed and developing world to support the use smartphone based decision support tools to facilitate task-shifting/ task-sharing functions to improve process of care or health outcomes, it is worth exploring the possibility of such a tool as it could integrate several features, viz., computation of personalized clinical management plan based on a clinical guideline, incorporation of an

electronic health record, and portability. All of these features are essential to develop an organized system of care in a clinic setting.

It is also worth noting the use of mobile phone technology in the Indian health system. The familiarity of the health workers in using computers to access an internet-based reporting system for maternal and child health programme and later switching the practice to a mobile phone-based reporting system was encouraging. The ability of health workers, who were relatively older and educationally less qualified, to adapt to an electronic reporting system demonstrated the scalability of mobile-phone based tools in healthcare interventions.

The results from HFA and the needs assessment exercise gave an insight to the functioning of the proposed CHCs where the intervention was to be developed and piloted. There were large gaps in adequate manpower, supplies and other logistics including supply of medicines. People with hypertension or diabetes require life-long medications which are often expensive and will have an impact on compliance to medicines particularly among poor socio-economic group. Unavailability of medicines or mismatch in the prescribed medicines with those in medicine supply at the hospital could often affect compliance among such patients. None of the facilities had Insulin in their drug supply which is far more expensive than other drugs and affordability is often a challenge to poor socio-economic groups. Similarly the lab facilities were inadequate to carryout laboratory investigations of blood glucose, cholesterol, lipid profile, kidney function tests, HbA1c etc. Such constraints translate to high out-of-pocket spending, as estimated at the national level that out-of-pocket spending accounts for 67% of the healthcare spending in India of which 74% is spent on drugs [72]. In this context, improving drug supplies and laboratory facilities within the timeframe of small pilot interventions has limitations as it involves huge cost to the government and also requires macro level changes in the system. Even if drugs and other facilities are made available,

addressing the shortage of manpower, with the deployment of trained nurses, will be most critical step in care provision.

Limitations

There were limitations to the Health Facility Assessment carried out because the number of health facilities covered and the staff who participated in the study were small in comparison with the fact that Himachal Pradesh itself has 76 CHCs. However, the CHCs in the Solan districts were relatively better in terms of facilities and manpower compared to CHCs elsewhere in the state (Personal Communication from the Chief Medical Officer, Solan). Further, the smaller number of doctors and nurses included in the in-depth interview can also be cited as a weakness. However there were ten doctors who participated in the interviews, including the Health Administrators of the district, and all of them had lengthy experience in the government service and had worked in several health facilities in Himachal Pradesh. Further, saturation principle was followed while interviewing the participants in each staff categories such as doctors, nurses and health workers and stopped recruiting additional participants for the interviews only after reaching saturation of inputs for several of the themes explored.

Conclusion

The CHCs in the Solan district of Himachal Pradesh had limitations in their capacity for providing optimal hypertension and diabetes care as per Indian Public Health Standards. In order to develop and pilot an intervention for hypertension and diabetes care, addressing the shortage of manpower is most critical and trained nurses could play an important role in it.

Chapter 6: Formation of a basic structure of the intervention package

6.1 Decision on the components of the intervention package

Deriving inputs from the Health Facility Assessment, the Project Steering Committee convened a meeting to decide on the components of the intervention. From the IDIs with the Medical Officers it was clear that, due to heavy workload, they would not be able to carry out a detailed patient evaluation, as per the clinical guideline and as used by the Decision-Support System (DSS) at the Out-patient Departments (OPD). It would necessitate additional manpower, such as a Care Coordinator, to play a facilitator role at the OPD, assisting the Medical Officer for patient screening, history-taking, clinical measurements and running the DSS. After careful deliberation, the Project Steering Committee decided to choose nurses (nursing diploma holders) as Nurse Care Coordinators (NCC) based on the following criteria.

1. Nurses with diploma have higher educational qualifications compared to health workers
2. Health workers are in short supply because the government has stopped training them, whereas plenty of nursing colleges in Himachal Pradesh and neighbouring Haryana are producing enough nursing diploma holders
3. The new national programme plans to establish NCD clinics at the CHCs. with a dedicated nurse. Therefore, the choice of a nurse provides an opportunity for scaling – up the model.

Since no standard clinical guidelines were in use at the CHCs, the committee decided to formulate a clinical management guideline to standardise the practice patterns and prepare training modules on the intervention, with special emphasis on training needs identified.

The committee added two additional components to the intervention, a behaviour change counselling service for patients to support the therapeutic lifestyle change suggestions given as part of the management plan and an insistence on a three-month follow-up advice, failing which, making a telephonic reminder to patients to ensure compliance.

In order to ensure referral care for complicated cases of diabetes and hypertension, the committee decided to include two outpatient departments run by specialist physicians at the Regional Hospital Solan (RH Solan) to provide referral care from the CHCs, along with the use of an advanced clinical management guideline for diabetes management with the deployment of a point-of-care HbA1c analyser and a more sophisticated DSS that runs on the advanced clinical management guideline.

The committee also decided not to simultaneously launch the community outreach component to link the patients with the respective health workers in the sub-centre area to which they belonged. This was due to the fact that the existing health workers were already overburdened with their job responsibilities and were not able to take on additional tasks. Further, the plan to include SMS reminders to alert the patients on drug intake and follow-up visits was dropped due to a change in government rules which enforced a restriction on using bulk SMS services for mass SMS broadcasting.

In summary the components of the interventions were:

- A Nurse Care Coordinator (NCC) to attend hypertension and diabetes patients at the OPD
- A structured training for the Medical Officers and NCC involved in the intervention
- A clinical management guideline for hypertension and diabetes
- A Smartphone decision-support tool for the healthcare team
- Counselling services for patients on diet, tobacco, physical activity and compliance to medicines

- A follow-up plan for the patients

6.2 Development of the clinical management guideline

From the baseline Health Facility Assessment it was noted that no clinical management guidelines were in use for hypertension/diabetes care at primary care in Himachal Pradesh. In addition, the lab facilities of the CHCs were not conforming to Indian Public Health Standards and were not equipped to conduct advanced investigations, such as glycaeted haemoglobin (HbA1c), which is used in recent guidelines on diabetes management. Recognising these facts, a committee was formed, with experts from the Centre for Chronic Disease Control (CCDC) and the All India Institute of Medical Sciences (AIIMS) to develop context-specific guidelines suitable for use in Himachal Pradesh. I reviewed the past exercises in India that attempted developing clinical management guidelines on hypertension and diabetes for the use at primary care settings in India, and provided necessary inputs to the Expert Committee. These included the exercise they carried out for the National Commission on Macroeconomics & Health and later for the Ministry of Health and Family Welfare, with the support from the World Health Organisation – India Office. The recommendations from the above activities were adopted by the Government of India in 2009 and were issued as a guideline for use by Medical Officers at primary care level as part of the National Program for the Prevention and Control of Cancer, Diabetes, Cardiovascular diseases and Stroke (NPCDCS). The Expert Committee decided to adopt the hypertension management guideline as such while the diabetes management guideline was modified to suit the local context. The detailed clinical management guideline recommended by the expert committee is appended (Appendix-4).

6.3 Development of the Decision-Support Software tool (DSS)

After finalizing the clinical management guideline, a software development firm (Data Template Infotech Pvt Ltd.; http://www.datatemplate.com/) was approached for converting the guideline into a decision-support software tool (DSS). It was decided that the DSS should have four essential features: 1) computation of personalised management plan based on patient parameters; 2) capability to synchronize with a central database; 3) search capability to find details of previous visits of patient records during follow-up visit; and 4) security features to prevent unauthorised access to patient data. Based on these requirements, the specification of the hardware and technology was worked out.

6.4 Selection of Hardware and Technology

In consultation with the software developers, Android platform was chosen because of its larger share of the Smartphone market and the cheaper price of Android devices compared to ones running on other operating systems. Gauging the user requirements and technical demands of the software, a minimum hardware specification was derived for the Smartphone device (see Table 6.1). Further, a needs assessment exercise was carried out with the healthcare team at CHC during the HFA which indicated the requirement for a dual SIM phone in order to avoid the need for carrying two handsets (personal and official) and, accordingly, Samsung Galaxy Y Duos GT-S6102 – a cheaper, dual SIM, touch-enabled, GSM Smartphone - was chosen as the device. Further, PhoneGap and SQL Lite (local mobile database) were chosen as technologies for the Mobile Client, while Java J2EE, Spring, Hibernate, Jboss, SOAP (Web services) and MySQL (Database) were chosen for the Server Application.

Table 6.1: Hardware specification for the handheld tool

Features	Recommended Minimum specification
GSM & EDGE Band	850 / 900 / 1,800 / 1,900MHz Dual SIM
Operation System	Android 2.1 or above
Browser	Android Browser
User Interface	Capacitive Touch Screen
Battery Capacity	1300 mAh or above
Built-in Memory	100 MB or above
External Memory using SD Card	4 GB or above

6.5 Process followed while developing the DSS

With the software developer team, a needs assessment was conducted to design the interfase and layout of the software. The logical flow of the interphase was designed in the following sequence:

1. Log-in Screen
2. Collection of basic demographic details of patient
3. History of disease and comorbid conditions
4. Clinical and biochemical information – (height, weight, waist circumference, blood pressure, blood sugar)
5. Summary of patient details and diagnosis
6. Treatment plan prompt

Using the above sequence, prototype software was developed out of the clinical guideline, which had 42 elements for data entries. The prototype was then tested by developers using their in-house software testing team for errors in the provided software codes and logic. The tested beta version software was further tested by two researchers for the accuracy of the

treatment plan generated from it, using 132 scenarios possible from the clinical management guideline.

6.6 Field testing of the DSS

After rectifying the errors detected in the beta version, the beta version was put out for field tests (user acceptance testing) with the help of two nurses. The nurses were asked to use the DSS at the OPDs for their feedback on the ease of using the software, suggestions for changes in the interface and lay-out, performance feedback and extent of comprehension of various inputs and outputs of the software. The field testing provided rich input to improve the ease and reduce the time spent on the software. The field testing came up with the following suggestions:

- Completely eliminating dropdown menu and replacing it with pre-selected radio buttons, particularly for dichotomous variables;
- Changing the background of the application to black to increase visibility during bright sunshine; and
- Addition of error checks for numerical variables, such as blood pressure, weight, etc.

Incorporating these feedbacks from the nurses, the mPower Heart DSS version 1 was released for deployment. In addition, a server application, using mysql server database, was also developed for synchronizing the client application running in the Smartphones. The server application was hosted in a dedicated server secured with firewall hardware and user-authentication at the Centre for Chronic Disease Control, New Delhi.

6.7 Deployment of the software and challenges faced

Along with the commencement of the hypertension and diabetes intervention, the mPower Heart DSS (version 1.0.0) was deployed in eight Smartphones for use in eight clinics at the five CHCs and the Regional Hospital of Solan (RH Solan), District of Himachal Pradesh.

Eight Nurse Care Coordinators (NCC) were newly recruited for these clinics for the study, and were trained centrally in using the DSS. The doctors were also given training on DSS and its features. Non-participant observation was made on the use of DSS by the Project Coordinator and the Project Manager and the NCCs were told to record any difficulties they faced while using the DSS.

After a month's use of the DSS, the NCCs reported that, due to large number of data elements to input in the software (36 data elements), it was slowing down patient flow at the clinic, risking the cooperation of the physicians. Based on this input, it was decided to rejig the software. We found that 13 data elements could be reduced (see Appendix – 5 for list of data elements), taking into account that NCCs, with their level of training, were unable to assess certain conditions (e.g. evidence of left ventricular hypertrophy, evidence of hypertensive retinopathy, evidence of atherosclerotic plaques in carotid, etc), while some of the data elements had minimal or no impact on choosing a management plan. The final list of data elements was prepared and given to the review of the Expert Committee and, as per their suggestion, the assessment of conditions that were beyond the capabilities of the NCCs was assigned to the Medical Officers for clinical judgement and to make changes in the management plan, if required. This suggestion was conveyed to the Medical Officers at the CHC for their approval and, with their approval, a major rework in the DSS was decided. Subsequently, after two months of deployment, a new version - the mPower Heart version 2 DSS - was released with 23 data elements and was deployed at all the eight clinics, along with a new server application. Seven more minor iterations were made to the DSS, necessitated by the demands from clinics and the most recent version in use is mPower Heart version 2.1.5 DSS. The versions and the list of changes made are shown in Table 6.2 and a schematic diagram of the process followed in the development of DSS is shown in Figure 6.1.

Figure 6.1: Process followed in developing DSS

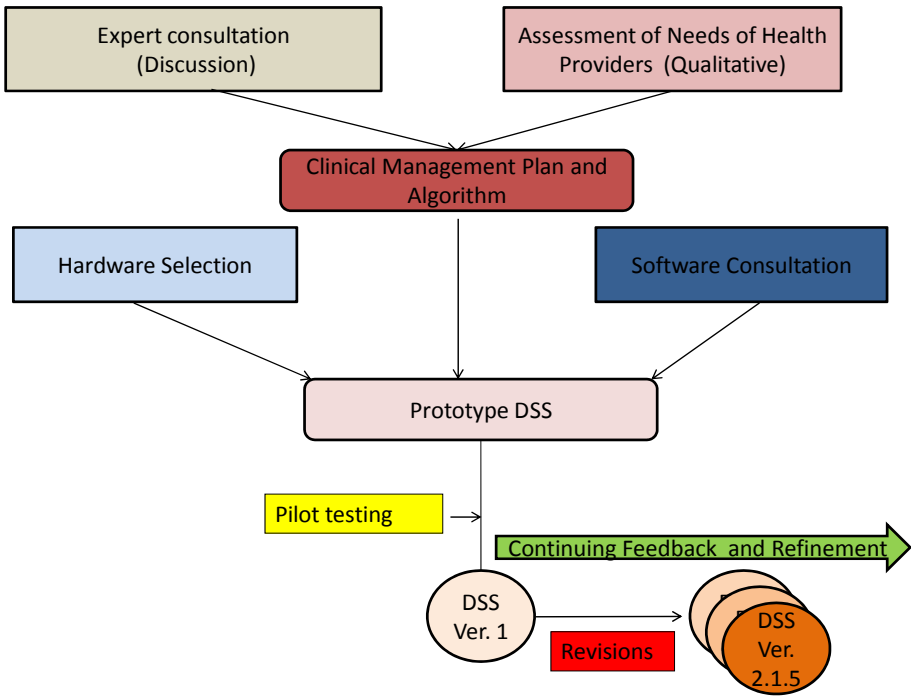


Table 6.2: Details on iterations made in the smartphone based decision support tool

Version No	Changes made
1.0.0 (Phone Gap Platform)	Deployment of mHealth production version 1.0.0
1.0.1	Added text area highlighting feature, Increased font size, Included numeric keys for numeric fields, Modified result page.
1.0.2	Text area highlighting with focus. Increased font size, Modified result page, Made interview details in single page.
1.0.3	Modified checkboxes (with buttons), Merged patient history.
1.0.4	User interface changes for fast navigation, Included buttons for checkboxes, Drop downs replaced with radio buttons, Interview date kept static, Added all UI changes to 3/6/12 visits.
1.1.0	Changes in the clinical algorithm

Version No	Changes made
1.1.1	Changes in login form, Changes in preview screen, Added Multiple visits data form, Feature to save data without analysis, Changes in Medical Officers comment section, Edit feature to partially saved data, New options to view saved data.
1.1.2	Changes in Medical Officers comment section, Feature to edit partially saved data, View option for saved data.
2.0.0	Name changed from mHealth to m-Power Heart, Change in logos & icons, Reduced the number of variables, Modified the algorithm, Search functionality included in the 'All Visitors' page for better usability, (Search Filter includes-Patient ID, Patient Name, Village Name), Automatically upload the completely saved patient information, Deleted manual upload option, Included field value ranges, Merged diabetes risk calculator with current application, 3 Options included: New Visitor (add new patient); All Visitors (Local Patient data); and Search option (from Server), Added multiple visits data capturing option (10 visits), Auto upload (manual upload removed) option included.
2.0.1	Included edit option for the patient data, Included subsequent visit synchronization feature.
2.1.0	Two more options included: Search DHC (Referred Patient tracking); and Updated client (Desktop Connection) Referred patient tracking, Feature for downloading and viewing the DHC details, Synching and viewing the data from the CHC desktop (2-way synchronization), Modified tailored messages for certain scenarios.
2.1.1	Defect fixes (proper interviewer name is displaying)
2.1.2	Defect Fixes (Synchronization)
2.1.3	Defect Fixes (Synchronization) Notification included for: 1. Total Patients to upload 2. Successful upload 3. Unsuccessful upload 4. Zero Kb files
2.1.4	Defect fixes (Synchronization)
2.1.5	Defect fixes (Synchronization) Current version

6.8 Development of training manuals for physicians and nurses

The HFA and the IDIs identified the requirement of additional training for the members of the healthcare team in order to deliver hypertension/diabetes care. To address the training needs and to explain various components of the intervention, two modules were chosen to be developed. A writing team of two medical graduates was constituted for authoring a training manual. The team reviewed the literature and made a draft outline of the module from various topics identified from the literature. Further, the results from the HFA were also fed into the training manual. The outlines of the modules were reviewed by the Expert Committee for their comments and approval. Subsequently, the two modules were prepared, one each for the Medical Officers and the Nurse care coordinators, and were again reviewed and finalised by the Expert Committee.

6.9 Process by which a new workflow developed

I visited all the CHCs to observe, understand and map the workflow at the OPDs of the CHCs and the RH Solan. The patients attending the OPDs first approached the OPD counter to register their name and get an OPD card; they then waited outside the consulting room of the Medical Officer for their turn. The patients followed a ‘first-come-first service basis’ to enter the doctor’s consultation room. Following his/her clinical examination, the doctor prescribed medicine by writing the list of medicines on the OPD card and the patients took this to the Pharmacy for medicines, dispensed free of cost, if supplies were available (see flow diagram, Figure 6.2).

Figure 6.2: Original workflow at CHCs

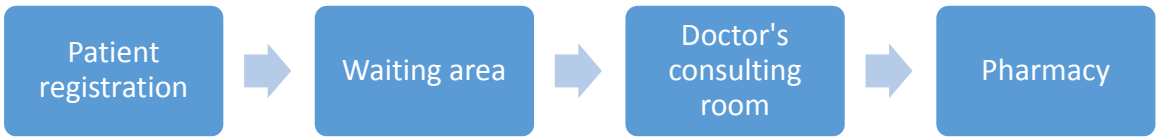


Figure 6.3: New workflow option 1

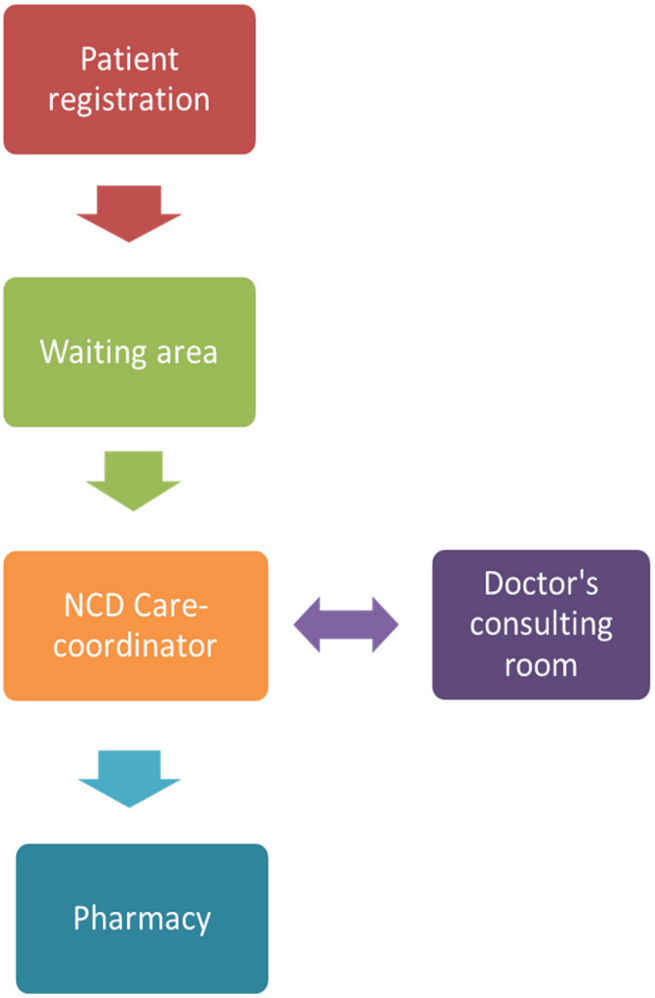


Figure 6.4: New workflow option 2

The mapping exercise was done to position the new NCC within the workflow and integrate the intervention-related additional activities into routine workflow with the least alteration and difficulty for the patients. The ideal scenario would be patients meeting the NCC before they met the doctor, so that the NCC could screen and identify high risk patients and known

patients coming to the OPD, and conduct their history-taking and evaluation (see flow diagram, Figure 6.3). Such patients could then meet the doctor for approval of the treatment plan generated by the NCC using DSS, or for additional investigation or modification of the DSS-generated management plan, as decided by the doctor. Subsequent to this step, the patient has to go to the NCC again to record any changes made by the doctor to the management plan into the electronic health record, as well for counselling on lifestyle changes and advice on consuming prescribed medications. We then consulted the staff, explaining the intervention activities to them in order to collectively decide the new workflow.

We found that at three OPDs from CHCs – Dharampur, Dharlagarh and Syri – there was enough space (a minimum area of 6x6 feet) to accommodate the NCC in a separate room and keep the equipment (weighing scale, stadiometer) and a small table and two chairs to seat the patient to measure their blood pressure (see flow diagram, Figure 6.3). In the remaining five OPDs of CHCs Nalagarh, Kunihar and the RH Solan, the NCC had to share the space with the doctor in their consultation room, because of space constraints (see flow diagram, Figure 6.4).

6.10 Design of an NCD OPD card

Since the Medical Officers were reluctant to use Smartphone DSS, conveying the patient information on screening, clinical examination and DSS outputs from the NCC to the doctors was found to be challenging, which otherwise would have been smooth by using either using Bluetooth or wireless technology to transfer the information between the NCC's Smartphone and the doctor's. As a solution, an NCD OPD card was designed in such a way that a maximum of number of patient details and DSS prompts could be imputed using tick marks to reduce time spent on filling-in the card. The NCD OPD card was prepared by the NCC and only given for hypertension or diabetes patients.

6.11 Description of the final outline of the intervention developed

In all CHCs the newly developed intervention resulted in a change in workflow. A detailed description of the new workflow is given below. Patients coming to the CHC first approach the registration counter, from where they receive an outpatient card which records their name, age and address. All the patients above the age of 30 are directed to the Nurse Care Coordinator for screening of hypertension/diabetes. The NCC assesses their demographic details, medical history, and anthropometry, and finally measures blood pressure. Subsequently the NCC feeds this information into the DSS tool to generate a personalised patient management plan. The DSS-generated patient management plan is then recorded onto a custom-made NCD OPD card and handed over to the patient. In the next stage, the patient approaches the medical officer along with the NCD OPD card. The medical officer either approves the management plan or modifies/rejects it according to his/her clinical judgement and records it in the NCD OPD card. The patient is then directed to the NCC, who then adds the decisions of the doctor to the electronic patient record generated in the DSS for future reference. The NCC then provides health education/counselling to the patients on drug intake, compliance, tobacco cessation, abstinence from alcohol, healthy diet and physical activity and finally a follow-up plan for future visits to the OPD.

Screening results in four group of subjects: 1) Those who screen positive for hypertension; 2) Those who screen positive for diabetes; 3) People with previous diagnosis of hypertension/diabetes or follow-up cases; and 4) Those who screen negative. At the time of screening, depending upon the blood pressure level, patients who screen positive for hypertension are advised to re-visit for a confirmatory diagnosis, or put on hypertension management immediately, or referred to higher centres (in hypertension emergency cases). Patients who screen positive for diabetes are advised to revisit the OPD in a fasting state for

confirmatory lab diagnosis. After confirmatory diagnosis of diabetes, the NCC generates a management plan using DSS for the concurrence of medical officer. People with previous diagnosis of hypertension/diabetes or follow-up cases visiting the CHC approach the NCC directly. Modification in their medication dosages are decided with the help of the DSS, which calculates the optimal dose depending on the clinical and laboratory values observed during that visit.

Chapter 7: Evaluation of the adoption stage of the intervention

7.1 Sources and procedures used to approach and involve the health system administrators/ management for their support and to become effective members of the project

The steps adopted to involve the Health Administrators and management have already been described in section 5.1. In summary, the following steps helped to assure support from higher levels:

A high level meeting with the Principal Health Secretary, seeking support and cooperation from the government to implement the mPower-Heart Project in the state was the first step, followed by an official letter to the Health Minister requesting permission to conduct the project in the Himachal Pradesh health system, with substantiating facts in support of the request. Subsequent to the meeting and the formal request, the Director of Health Services issued the permission letter. However, there was a delay of four months in obtaining permission due to a change of the person in charge of the Principal Secretary.

All the necessary permissions were obtained from the state authorities prior to initiating the project. The official orders to the district authorities and the Block Medical Officers were key to obtaining support from the health system. Further, the Health Department designated a Liaison Officer for day-to-day interaction with the government.

Periodic interaction with the Liaison Officer ensured support from the state authorities for the project. Updates on the progress of the project were regularly communicated to the Liaison Officer and a mid-term progress report was submitted to the government.

7.2 Sources and procedures used to approach and involve the healthcare team for their support and to become effective members of the project

The process by which the healthcare team was made members of the project and its support gained for implementing the project is described below.

Formal support through official orders obtained from the state authorities was the first step in assuring support from the project. On receiving orders from the Director of Health Services, the CMO issued office orders to the BMOs and discussed these in the monthly planning meeting held at the District Headquarters in order to kick-start the project. The Study Coordinator and the Project Manager attended the monthly meeting, during which the CMO introduced the project leads to the BMOs and ensured the full support and cooperation from the health system.

Visit to the facilities and interaction with the healthcare team was the next step. The Study Coordinator and Project Manager visited all the CHCs and interacted with the healthcare teams and discussed in detail about the project. In consultation with the respective BMOs, decisions were made on the implementation plan, staffing, patient management issues and supervision for the project at each CHC. Since the BMO holds the authority for CHCs, BMOs oversaw the process, such as assigning the project-related responsibilities to a Medical Officer attending OPDs, arranging space for staff and preparing the supervision plan.

A supervision plan was developed in the meeting with the BMOs. It was decided that the NCCs would report to the Medical Officer, who was assigned with the project-related responsibilities. The NCCs would prepare monthly reports on the project activities at their respective OPDs. The Project Manager would consolidate the facility level data and would provide the monthly feedback to each of the BMOs, which would be reported to the CMO in

the monthly meeting at the District Headquarters as part of project monitoring. Further, the Project Manager was also to provide feedback on shortages of medicines in supply and lab facilities to the BMO, to support the smooth implementation of the project activities.

A training meeting was organised for the healthcare team at the District level, inviting the BMOs and the Medical Officers of the CHCs. In addition, the CMO sent out a circular to all the BMOs to send the Medical Officers responsible for implementing the project at the respective CHCs to the training programme. A total of eight Medical Officers from CHCs, two Block Medical Officers, two specialist physicians from Solan Regional Hospital, the Chief Medical Officer and the District Health Officer attended the training meeting before the project launch.

A teaching faculty, comprising Prof. Nikhil Tandon (Professor of Endocrinology and Metabolism, AIIMS), Prof. D. Prabhakaran (Former Additional Professor of Cardiology, AIIMS), Prof. P. C. Negi (Professor and Head of Cardiology, IGMC, Shimla), Dr. Ambuj Roy (Associate Professor of Cardiology, AIIMS), and Dr. Rajesh Khadgawat (Associate Professor of Endocrinology, AIIMS) delivered the training sessions.

Training of Nurse Care Coordinators

The training of Nurse Care Coordinators was conducted over seven days in three sessions. The first session lasted three days and NCCs were trained in identification of high risk subjects of diabetes and hypertension, diagnosis and comorbid conditions, management plan, drugs and their indications, counselling skills and behavioural change communication, interactive practical management of hypertension and diabetes and case studies. This session was conducted in August 2012.

The second session (September, 2012) was of two-day duration and focussed on training the NCCs in the DSS software and measurement of clinical parameters such as height, weight, waist circumference and blood pressure values.

The third session was conducted in October 2012 and lasted for two days, with refresher training along with case studies and solving of problems faced by the NCCs during their time at the CHCs.

7.3 Sources and procedures used to inform and involve patients for participation in interventions

In order to inform and involve the patients in the intervention, the following strategies were used in consultation with the healthcare team:

A poster was prominently displayed at the hospital to inform patients about the on-going project. Further, inside the consulting room another poster that described the importance of lifestyle measures for prevention and control of diabetes was displayed and carried the logos of the project, the partnering institutions and the Government of Himachal Pradesh. The Nurse Care Coordinators wore a badge on their uniforms displaying the logo and name of the project. These methods were used to disseminate the information about the project to patients.

All the eligible participants were invited for opportunistic screening. This often raised questions from the patients about its purpose, because most patients come to the health facility seeking care for other ailments. The NCC explained the project to seek the cooperation of patients. Further, word of mouth publicity through patients was another channel for informing the community about the project and ensuring participation of the patients.

Chapter 8: Evaluation of the implementation stage of the intervention

8.1 Introduction and Objectives

After completing the design of the intervention, the mPower Heart Project began implementation at the CHCs. All the five CHCs – Nalagarh, Dharlagarh, Kunihar, Dharampur and Syri - were included in the implementation. Since the Nalagarh CHC had two OPDs functioning, the intervention was implemented in six OPDs. For ensuring referral care of complicated cases of hypertension and diabetes, two OPDs, run by specialist physicians at the Regional Hospital Solan (RH Solan), were also included. Thus, a total of eight OPDs were covered in the project from six health facilities. Eight trained Nurse Care Coordinators were deployed at all the eight OPDs, along with DSS tool, equipment, and NCD OPD cards. The evaluation of the implementation started simultaneously with the pilot implementation, which was conducted over eight months. The objectives of the evaluation of the implementation stage of the intervention were:

1. To evaluate the implementation of the intervention at the level of the health organisation
2. To evaluate the implementation of the intervention at the level of the healthcare team
3. To evaluate the implementation of the intervention at the level of patients
4. To identify the determinants that play a role in the implementation of the intervention
5. To determine the scalability of the intervention by assessing stakeholder perspectives

8.2 Detailed Methodology

Following the conceptual framework described in Chapter 5, the evaluation of the implementation was carried out at different levels - healthcare organisation, healthcare team and patient level. Mixed methods were used for the evaluation, using quantitative data

pertaining to process and health outcomes, as well as qualitative data from non-participant observation of the intervention, and by conducting in-depth interviews with the healthcare team and patients. To determine the scalability of the intervention, only qualitative data from the in-depth interviews was used. The evaluation components for implementation of the intervention, their definition and methodology used are given in Table 8.1.

Table 8.1: Definition of evaluation components at different levels and data collection method

Stages of intervention development	**Definition of evaluation component at different levels**	**Data collection method**
Implementation	Healthcare organisation level	
	Providing the intervention to the health facilities and members of the healthcare team	Observation, In-depth interviews
	Healthcare team level	
	▪ Numbers of the healthcare team approached as members of the intervention project; ▪ Numbers of the healthcare team who received training on the intervention; ▪ Opinion/satisfaction about the intervention and its components by the healthcare team ▪ Compliance to DSS-based clinical management plan; ▪ Effect of the intervention on outcome indicators	Observation, In-depth interviews; Assessment of hospital records
	Patient level	
	▪ Proportion of patients who received the intervention, including follow-up care ▪ Opinion/satisfaction of patients about the intervention	Observation, In-depth interviews, Assessment of hospital records
Continuation	Healthcare organisation level	
	Extent to which the interventions became routine and part of the everyday culture and norms of the organisation, including the degree to which interventions are continued.	Observation, In-depth interviews, Assessment of hospital records
Implementation determinants	All levels	
	1. Attributes of the socio-political context 2. Attributes of the organisation 3. Attributes of the healthcare team members 4. Attributes of the intervention	Observation, In-depth interviews

8.2.1 Qualitative component of the evaluation

Selection of the health facilities and participants

All five CHCs of Solan district where the intervention was piloted were included in the evaluation process, involving the healthcare team of these CHCs and the patients who underwent the intervention. In-depth interviews were conducted with all the members of the healthcare team involved in the implementation of the intervention at the OPDs. This included all six Medical Officers who were assigned to implementing the intervention, two BMOs, two specialist physicians running the specialist clinics at RH Solan, and all the eight Nurse Care Coordinators who were appointed for delivering the intervention. Further, in-depth interviews were conducted with patients selected from each of the five CHCs. Patients who were part of the intervention and had at least one follow-up visit prior to interview were eligible. For selecting patients from CHCs, data saturation principle was followed, interviewing consecutive eligible patients meeting the above criteria. On average, six patients were interviewed from each of the CHCs, selecting a total of 33 patients from all the CHCs. In addition, non-participant observation was also carried out to study the implementation process at the CHCs and to derive inputs for evaluation, along with examination of the health records at the CHCs.

Conduct of the interviews

Each potential interviewee was contacted by myself and invited to be interviewed at a time convenient to them. All the interviews with the Medical Officers and the Nurse Care Coordinators were conducted by me. The interviews with the patients were conducted by a trained research staff member, who I had trained using the interview guide and mock interviews. The interviews were conducted in settings ensuring sufficient privacy and confidentiality, after providing a brief description of the study and obtaining a signed informed consent of the participant. The interviews were conducted in Hindi or English and

were digitally recorded. The interview notes and recordings were reviewed on the same day itself, and themes and questions were further developed using an inductive approach to condense the raw information into a summary and to establish clear links between the research objectives and the findings. This approach enriched the data collection procedure, allowing for flexibility in themes.

Themes of the interviews

The themes for the IDIs were based on the objectives of the evaluation. The themes for the IDIs were based on the conceptual framework and evaluation methodology described earlier. Different themes were developed for Medical Officers, Nurse Care Coordinators and patients while observations and assessment of records of the health facility were employed for assessing the healthcare organisation level factors that affected the implementation process. Broadly speaking, themes were constructed for the IDIs around perceptions of the healthcare team on: 1) impact of the new intervention and its components on service delivery; 2) facilitators and barriers that were affecting the implementation of the intervention; and 3) perceived appropriateness of the new intervention within the work culture of the organisation and their opinion on continuing the implementation of the intervention at their respective health facilities.

In-depth interviews broadly focused on: 1) their opinion of the new intervention on service delivery from the health facility; 2) difficulties/discomfort faced or satisfaction as a result of being involved in the intervention; 3) perceptions on use of a Smartphone decision-support tool in care delivery. The interview notes and recordings were reviewed on the same day and themes and questions were further developed using an inductive approach. This approach enriched the data collection procedure, allowing for flexibility in themes.

Participant interviews were divided into an open and closed ended section. In the open-ended section, participants were asked to reflect on their experience and opinions about the intervention. Following the completion of the open-ended session, participants were led to additional themes, which were derived from the conceptual framework. The interview guide for each group is appended (Appendix-6)

Analysis plan

The thematic content analysis approach was used to explore the data, so that thick, rich descriptions could be identified to exemplify the multiple perspectives and realities of the sample for examining the specific themes explored in the in-depth interviews and deriving meaningful insights and interpretations [167]. Coding rules were established, including exhaustive coding, allowance for double-coding when appropriate and coding passages at the smallest level of meaning, using the qualitative research analysis software NVIVO 10. The specific analytic functions for which NVIVO was used were: 1) establishing the coding structure elements in an NVIVO analysis file; 2) coding each piece of in-depth interview transcripts and sorting; and 3) searching within the coded data. One coder (AVS) openly coded all transcripts to create definitions and a codebook. Memos were taken during this process. Each individual code was reviewed in full to assure proper placement of relevant text. Saturation was documented, following the first round of open coding. Following this, a draft codebook was created. One more coder (AAS) was trained in these definitions and engaged in AXIAL coding, whereby the coder applied these codes to the transcriptions. Myself and AAS reviewed codes to identify areas where they conceptually overlapped or could be brought together to form higher order themes. These themes were organised and described with the conceptual framework to narrate the results. In order to preserve anonymity in the use of quotes, the participants were given a tag combining their age, gender

and designation. Their specific role was not distinguished, as this would lead to the possibility of identifying a specific person.

8.2.2 Quantitative component

The quantitative component of the study supplemented the assessment of the implementation of the intervention by collecting data on process as well as health outcomes pertaining to the intervention. Data on following outcomes were collected during the implementation of the pilot:

1. Number of patients attending the out-patient department (OPD) eligible for opportunistic screening
2. Number of known cases of hypertension / diabetes attending the OPDs
3. Number of new cases detected through opportunistic screening
4. Mean change in systolic blood pressure at six months of follow-up from the baseline
5. Mean change in fasting glucose level at six months of follow-up from the baseline
6. Follow-up rate achieved for hypertension and diabetes patients at six months of follow-up from the baseline

In addition to the above outcomes, to assess the extent of usage of the clinical management guideline used in the project, prescription patterns of drugs were collected for 100 consecutive patients from each of the clinics. Further, information on drug supply to each of the health facilities, which was found to be a crucial factor affecting the intervention, during the entire period of the project, was also collected.

Analysis plan

Quantitative data analysis was performed using STATA 10.0 (Statacorp Texas). Pre and post difference in outcome was assessed using t-test, while recruitment and retention of

participants was assessed by examining: number eligible to be recruited, number enrolled in the study and dropout from regular follow-up at the completion of six months.

8.3 Evaluation at the Health Organisation Level

The evaluation of the implementation of the intervention at the level of health organisation was carried out by non-participant observation of the degree of delivery of the intervention in all the clinics and by relating those observations with workload and the manpower available. Additional inputs from the evaluation were derived from conducting in-depth interviews with the healthcare team.

In all six OPDs of the CHCs and the two OPDs of the RH Solan, the intervention started with opportunistic screening for hypertension and diabetes in all the patients attending the OPDs of the CHCs. The clinical management plan was decided using Smartphone-based DSS in diagnosed subjects with the concurrence of the Medical Officer. Further, the NCCs were conducting counselling of all the patients on therapeutic lifestyle changes, compliance to medicine and follow-up.

During a period of eight months (Dec-Jul 2013), 56,814 patients attended the OPD at five CHCs, out of which 13,860 eligible patients (aged 30 or above) were identified and screened by NCCs for hypertension and diabetes. The number of patients attending the OPDs ranged from 40-150 patients a day. The patient load had a bearing on the implementation of the intervention. It was found that the optimal delivery of the intervention depended on the number of patients attending the OPDs in a day, in order to carry out all the planned intervention activities, such as opportunistic screening, patient evaluation using DSS and patient counselling. In CHCs Nalagarh and Kunihar, which had high daily attendance of 100 and above patients, the NCCs were unable to adequately conduct counselling on therapeutic

lifestyle changes due to time constraints. During in-depth interviews (IDIs) with doctors and NCCs, their opinion was sought to determine the optimal number of patients that could be managed by one NCC in a typical day at the OPD. Further non-participant observation was also made to quantify the optimal number of patients that could be handled by the NCC, considering the duration of OPDs in a day and average time spent by the NCC with each patient.

In the IDIs, the NCCs responded that the optimal number of hypertension/diabetes patients would be 20 a day and conducting opportunistic screening for another eligible 40 patients in the 30+ age group. This model would be suitable for OPD clinics where doctors and NCCs were sitting separately.

In other clinics where NCCs shared the work space with doctors, NCCs were attending to almost all the patients, explaining to them about their prescription, helping the clinicians in conducting history-taking and providing other assistance in clinical work at the insistence of doctors. In such clinics, the optimal number of patients was estimated to be 40. However, the Medical Officers were of the opinion that the ideal number of patients attending would be 25, in order to conduct detailed patient evaluation and management. A specialist physician made the following opinion:

"If we go for an ideal clinic, optimal number of patients would be 25, beyond which quality will deteriorate."

8.4 Evaluation at the Healthcare Team Level

8.4.1 Numbers of the healthcare team approached as members of the intervention

The Indian health system operates in a top-down approach with strict hierarchy and command control. Hence, the involvement of the Medical Officers was not voluntary, but mandatory. In all the five CHCs (except CHC Dharlagarh, which had only one Medical Officer), the Block Medical Officer who was in charge of the facility assigned responsibilities for implementing the project to two Medical Officers. All the nine Medical Officers who were approached for participating in the intervention complied with the project during the entire duration of their tenure at the CHCs. Three Medical Officers who attended the initial training did not continue till the end of implementation evaluation, due to transfer and replacement-postings, which frequently occur at government hospitals. The new Medical Officers posted at the CHCs did not initially cooperate with NCCs in conducting opportunistic screening and patient evaluation. However, after attending a formal training sessions they participated in the project enthusiastically.

8.4.2 Numbers of the healthcare team who received training on the intervention

A total of 10 Medical Officers from CHCs and two specialist physicians from RH Solan attended the training sessions on the project. From all CHCs, except Dharlagarh CHC, two Medical Officers were assigned for training. This ensured that, even in the event of transfers or leave of absence, the delivery of the intervention was not affected. Further, all the eight NCCs who were recruited and directly supported by the project were trained to deliver the intervention.

8.4.3 Opinion/satisfaction about the intervention and its components by the healthcare team

8.4.3.1 Opinions of Medical Officers about the intervention

IDIs were conducted with eight Medical Officers who were running the OPDs at the CHCs and the RH Solan. Doctors from all the five CHCs were of the opinion that the new project had led to detection of large number of unknown cases of hypertension and diabetes, due to screening activities carried out by the NCCs. The Medical Officers observed that the project had had a major impact on detecting new cases and improving the quality of service delivery. A Medical Officer said:

"Because of this project we are able to identify lot of patients with BP and diabetes because of the screening, which otherwise would have missed. Another thing to mention is the detection among younger age group, particularly in the 30-50 age group, because of screening.

Further, another Medical Officer stated:

"This project has been very beneficial for this CHC. The hypertension and diabetes care is now become very structured, mainly because of the dedicated staff we have for this. Now we do screening for patients and we are detecting new cases."

The doctors' narratives highlight that the major reason for the impact of the project was due to the appointment of Nurse Care Coordinators who performed additional activities, such as screening, history-taking, clinical measurements and patient counselling. They also helped the Medical Officer in managing other patients, which resulted in reduction in the workload

of the Medical Officer. For example, a Medical Officer said:

"We now have a NCC here full time as part of this project. She does screening, measures BP and she is very committed also and behaves well with the patients. Because of these, we get new patients detected and patient care has improved.
…….. she (NCC) does counselling and reduces my workload and is very helpful for me because I am the only Medical Officer here to handle the entire OPD".

The doctors also observed that, unlike in the past, the NCCs advised the patients verbally and wrote the dates for the follow-up visit on the OPD cards. They felt that those two instructions helped in bringing back patients promptly for follow-up visits and improved compliance to medications. A Medical Officer gave the following opinion:

"Follow-up of patients and compliance among patients coming to us also increased. This girl (NCC) knows how to bring back patients. She make specific advices and give some sample medicines we have here; She then insists patients to come back for the follow-up visits telling them that sample medicines are only for regular patients."

A specialist physician stated that:
"*Yes, compliance has increased. I find several of patients coming regular to me and checking their blood pressure; I find them having medicines regularly."*

The doctors also felt that the new clinical management guideline helped them improve their practice, because there were neither any such guidelines issued nor any training programme organised by the Health Department for doctors in chronic disease management. A Medical

Officer made the following statement about the project:

"The training and the manual you had provided and the software suggestions are very good. In our medicine training, we get a general training only. In that way it has helped improving my practice on choice of drugs and initiating drug therapy."

8.4.3.2 Opinions of the healthcare team about the impact of the DSS tool

The Medical Officers observed that use of the new DSS made patient evaluation more systematic and reduced the chances of missing important comorbidities while gathering medical history or crucial clinical parameters during examination. The doctors felt they benefited by the software, which was based on recent updates in medical guidelines. Further, all the Medical Officers agreed that the DSS was serving as a good tool for accessing details of the previous visits when patients came to the hospital without their OPD card. A Medical Officer made the following remark on the use of DSS:

"One change I can see is that we are ruling out the chance of missing any comorbidities."

Another Medical Officer stated:

"The recent updates taught in the training were very useful; For example, change of beta-blockers from the first line drugs. The software takes care of these medical updates and that way the new system is very useful."

Similar observation was made by another Medical Officer:

"Because of the software that you provided, we have a record of patients and that help us accessing the details of their previous visits. We also have record of the phone numbers of the patients and we can call them for follow-up visit".

The NCCs were also of the same opinion that that, apart from generating the management plan, the DSS served as a patient record. In their experience, many patients forget to bring the medical records of their previous visits, but they were able to get details of previous visit from the Smartphone DSS. A Nurse Care Coordinator said:

"The advantage is that it serves as a record in my phone, which the doctor demands frequently from me for patients who don't bring their previous records".

One of the Medical Officers cautioned us on the language used in the DSS prompts and suggested making necessary changes when revising the software. The system displayed prompts (such as High Risk for Diabetes; Low Risk for Diabetes), saying whether patients were at risk of developing diabetes based on a clinical risk score. The doctor cautioned during IDI that NCCs should be careful about passing on such terms to patients as it could make the patient apprehensive:

"Another point I have is; this software gives a 'High Risk' prompt *for diabetes. Unlike a word 'carcinoma' which patient doesn't understand, 'High Risk' is a word that can cause apprehension among patients. Some patients are very sensitive to such words. You need to tackle this issue."*

8.4.3.3 Opinions of the healthcare team about the new NCD OPD card

The clinical management plan and patient parameters were passed to the doctors using a new NCD OPD card. The NCCs observed that the doctors were getting all the patient details from the DSS in the newly designed NCD card, which was very convenient for them. A Nurse Care Coordinator had the following opinion:

The major help with this card is that the doctor gets all the details of the patients in the card, which makes his job easy. They don't have to do BP measurement or taking weight or history-taking. It is done by us and whole information is passed in the NCD card to the doctor.

The doctors also made similar observations that the new card was helping them, as it ensured that patient evaluation was done by the NCC in a systematic way. They also suggested printing lifestyle suggestions on the reverse of the card as a patient education tool. For example, a Medical Officer stated:

"Yes, this card has made the patient evaluation more structured; I can see whether the NCC had skipped anything in the patient evaluation.
…… Since we give this card to patients, why don't you print health messages on the other side of the card so that patients can read it and practice?"

A specialist physician made the following opinion on the NCD OPD card:

I get all the information in the card which makes things easy for me. Secondly, when patients come back for follow-up, looking at the date, I will know whether they are regular in their follow-up.

The NCCs also felt that patients were attributing special value to the new NCD card and most patients were bringing the NCD card along with them during follow-up visits.

8.4.3.4 Opinions of Medical Officers about the NCCs' role as facilitator

The Medical Officers were unanimous in their opinion that the facilitator role of the NCC was of great help to them at the OPD. NCCs were not only attending hypertension/ diabetes patients, but also helping doctors to manage patients with other ailments as well. In addition, they used to accompany doctors during their daily rounds to the in-patient wards, caring for patients with hypertension/diabetes. The facilitator role played by the NCC saved doctors effort and time. Further, patients also found that their complaints were listened to properly. In six months, the NCCs have established their presence and their roles have been identified by the community, specifically for diabetes and hypertension care. A medical officer readily made the following statements when asked about his opinion about the facilitator roles of NCCs in the OPDs:

"*We have mostly hypertension patients, but not many diabetes patients. In this busy OPD with 60-70 patients in the morning, NCC handles the initial history-taking and measurements and sends the HTN/DM patients to me along with the recordings in the OPD card. That way the patient evaluation is complete, which otherwise would not have been possible. Patient follow-up has also improved. She has the record of patient's previous visit and that helps me to assess control of BP and Glucose. Patients sometime forget to bring OPD card and the new system is very helpful in such situations."*

A specialist medical officer stated:

"They are well trained and help me in OPD as well as during my rounds. They do screening before I sit in the OPD, do all the measurement and that makes the job easy for me. Now villagers know that they get BP check-up here and are coming here to do that. They are even ready to wait for BP measurement and treatment. I should give credit to these girls for their approach and manners."

Another specialist medical officer stated:

"NCCs, they are really helping. I would say we are lucky to have them here. The speed with which I dispose patients has increased because of them. They sort the lab details from the reports on blood sugar level, height everything and I just need to quickly go through. So it is very helpful. Patients also feel good because their complaints are listened properly."

8.4.3.5 Doctors' opinions about the counselling services carried out by the NCC

Due to the limited time available to them to spend with each patient, the doctors, were unable to explain to each and every patient in detail about medications and the importance of lifestyle changes. They were happy that NCCs were fully handling patient counselling, which is as equally important as prescribing medicines, and were impressed by the services of the NCCs. A specialist medical officer made the following observation:

Yes, I find the counselling of NCC very effective. They really spend time and put effort to educate patients and patients do take medicines. One thing I noticed is that they educate the relatives, particularly youngsters, who accompany the patients; that have a high impact on compliance. Now NCCs have started calling patients for follow-up. That is in a way benefiting patients.

Although counselling services were running successfully in all the CHCs, it could not be implemented in the two specialist clinics at the RH Solan, which had high number of patients with hypertension or diabetes. The specialist physicians there were not in favour of NCCs spending time on counselling for more than two minutes, because that could result in the piling-up of patients. A specialist medical officer raised the following concern:

"It is not possible to have a 10 minute spend on counselling here. Our workload is so much that we have to see 100-150 plus patients every day. To counsel properly on lifestyle modification, diet modification, and about medicines it requires at least 10 minutes and it requires separate sitting place. Here, each patient get roughly two minutes; I won't be able to allow NCC to take more than that because my speed will also reduce."

8.4.3.6 Skills learned by NCCs from the project and perceived additional training requirements

The NCCs who joined the project were fresher who underwent three training sessions during the project in order to equip them to deliver intervention.

During the post-intervention IDIs, they were asked about what they had learned during the course of the project and what additional things they needed to learn to improve their performance. The NCCs responded that they felt the training in the project and the experience from it had helped them to improve their knowledge and skills. Further, the interaction with the patients and the mentoring from Medical Officers helped them to answer many of the queries they receive from patients, which was the most difficult part. The narratives of a NCCs depict how she gained confidence to manage patients:

"The duties I do in this project were not taught in our GNM course (General Nursing & Midwifery). I learned a lot from the training we had. The doctors also explain me when we get new cases and that also increased my knowledge. Each time when I talk to patient I am getting newer questions; I need to give them the correct answer and initially that was the toughest part; I used to ask our doctor and learn from them to answer such questions. This way I have learned a lot about hypertension and diabetes."

Another NCC said:

"We learned a lot of information about the diseases and doctors also trained us a lot. Initially I was not sure what to counsel patients. After the project training, I was able to explain things clearly to the patients. I got knowledge about the diagnosis, composition of the medicines, normal values and I am confident now in managing patients. My mummy is a diabetes patient and I can explain her and we have 12-13 patients in our neighbourhood. I give advices to them as well".

The NCCs wanted refresher training every six months. They also asked for additional training on other cardiovascular diseases, such as myocardial infarction and heart failure, which they frequently encounter at the OPD, and to be able to answer queries from such patients. Further, the NCCs wanted to learn insulin therapy, which they were not doing at the CHCs because of insufficient/absence of supply. One of the NCC said:

"I want to learn more about insulin treatment. Some patients ask me about that, but I don't have much knowledge about that. Then some patients ask me why their BP is not reducing even after they are on drugs. I want to know the answers to these questions."

Similarly, the NCCs wanted refresher training on management of heart diseases as well. One of the NCCs stated:

"Sir, we are getting cardiac patients in the OPD a lot. We need training about that disease as well, so that we can attend to them also in a better way by giving advice to them or explain the drugs, its administration and how to follow-up."

8.4.4 Compliance to the DSS-based clinical management plan

We asked the Medical Officers about the extent of use of the clinical management guidelines which were provided as part of the intervention. All the Medical Officers were of the opinion that they were not always able to comply with the suggestions from the DSS in treating patients. The reasons cited for non-compliance were mismatch in the availability of medicines at the hospital versus DSS suggestions, or the affordability of medicines (for example, calcium channel blockers are cheaper compared to ACE/ARB group medicines). During IDI, a Block Medical Officer said:

"I try to follow the guidelines as much as possible. I have made changes in the choice of drugs, but can't say I go by them all the time".

A Medical Officer said:

"The new clinical guideline is very useful and it is very straightforward; but first line medications like ACE-I are expensive and poor can't afford it unless we have it in our supply; then we go for Amlodipine, which is cheaper. If you have provision for drug supply, we could completely implement it."

To study the extent to use of guidelines for prescribing medicines, 100 consecutive prescriptions from each of the OPDs of the CHCs and RH Solan were studied. It was found that 73% of the prescriptions from the OPDs of CHCs matched clinical management

guidelines. However, the prescription pattern at the specialist clinics of RH Solan were deviant from the clinical management guidelines, with only 63% of prescriptions in agreement with the DSS suggestions derived from the clinical management guideline (see Table 8.2). When the specialist physicians were asked about the reason for deviation in their prescriptions, they responded that many of the patients they treat have complications and comorbid conditions and, for such conditions, they use newer and expensive medicines to achieve quick response to therapy. Another reason for using newer expensive medicines, deviating from the guideline, was the tendency to stay on par with the prescriptions of their peers in the nearby tertiary care centres, such as IGMC Shimla and PGI Chandigarh. The doctors felt their reputation would be threatened if they switched to low cost medicines and this concern was also expressed by specialist physicians during training sessions at the time of the project launch. Two specialist physicians made the following statement during IDI:

"We can't follow your guideline fully because we cater to different category of patients. I told you this at the training itself. We are getting patients with glucose values of 450 or above and we can't go by metformin and glipicide, which the guideline says. When patients come from faraway places, we prescribe medicines using our clinical judgement without waiting for the lab reports. We will adjust dosages or drugs when they come next time with lab results. Patients can't wait for that long because of the travel time and associated difficulties".

Table 8.2: Comparison between prescription pattern at the OPDs and the suggestions from clinical management decision support system

Name of OPD	Total Prescriptions	No of Prescriptions in agreement with DSS	% agreement
Kunihar	100	94	94%
Dharlagarh	100	99	99%
Nalagarh 1	100	92	92%
Nalagarh 2	100	90	90%
Dharampur	100	45	45%
Syri	100	18	18%
RH Solan 1	100	66	66%
RH Solan 2	100	59	59%
RH Solan Total	**200**	**125**	**63%**
Total - CHC OPDs	**600**	**438**	**73%**
Grand Total	**800**	**563**	**78%**

8.4.4.1 Opinions of the NCCs about the use of guidelines by doctors

The NCCs were asked about the adherence to the clinical management plan, generated from the DSS software, by the doctors. Their opinion was similar to what the doctors expressed in the IDIs. The specialist doctors at RH Solan were using expensive and combination medications, while doctors at CHCs were following the guidelines most of the time. The reason for deviation was mainly due to unavailability or mismatch in availability of medicines in the drug supply. A NCC placed with a non-specialist Medical Officer stated:

"Our doctor writes mostly the drugs as per the guideline. For poor patients he gives drugs available in the supply which is free rather than advising medicines suggested by the software."

In contrast, a NCC placed with a specialist physician stated:

"Here specialist attends diabetes and hypertension patients. He doesn't follow the drugs from the guideline for diabetes patients. He prescribes different drugs."

8.4.5 Effect of intervention on outcome indicators

Since the full launch of the intervention in Dec 2012 at five CHCs, a total of 56,814 patients have attended the six OPD clinics for eight months, out of which 13,860 subjects aged 30

years or above formed the eligible group for opportunistic screening (see Table 8.3). The proportion of the eligible group for opportunistic screening was 24.4%. From the screening of the eligible group, 5086 (36.7%) subjects were identified to have either hypertension or diabetes, or both. This group comprised of 2469 (46%) known cases and 2,617 (54%) newly-detected cases (see Figure 8.1). The proportion of newly-detected cases out of the eligible group ranged from 32.6% in CHC Syri to 48.1% in CHC Dharlagarh (see Table 8.4).

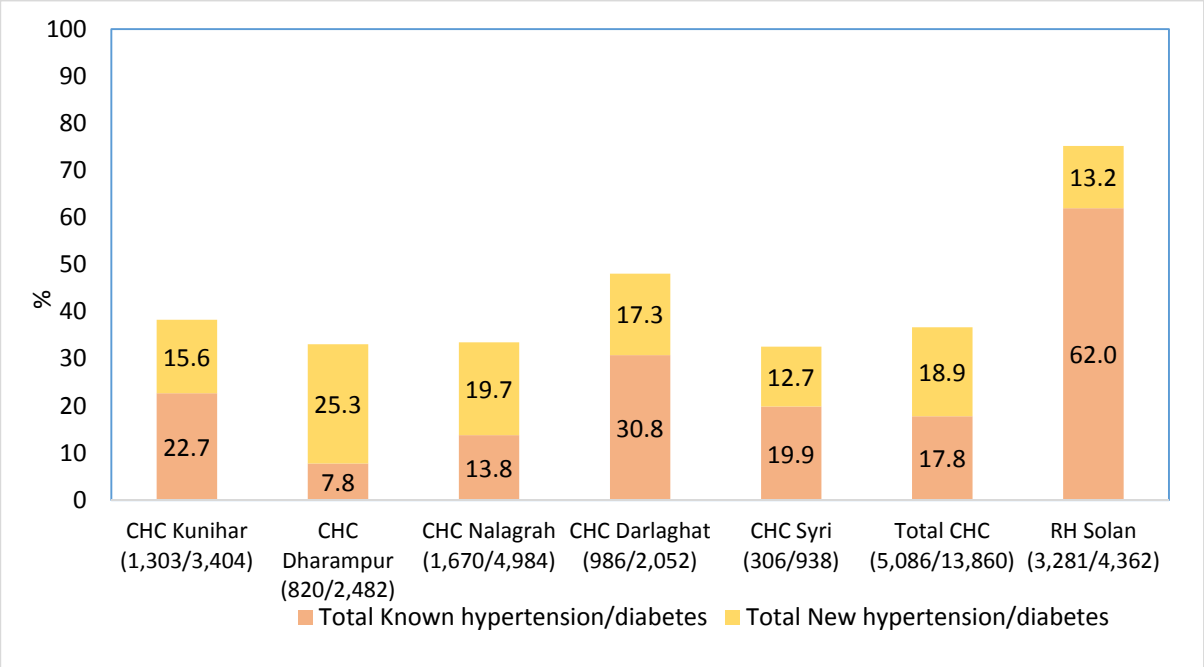
Table 8.3: Details on the number of OPD visitors at various health facilities

Name of the facility	Total OPD	Eligible group for screening	No of Known HTN cases	No of new HTN cases	No of Known DM cases	No of new DM cases	No of Known HTN & DM cases	No of new HTN & DM cases
CHC Kunihar	15315	3404	502	455	143	46	127	30
CHC Syri	4281	938	170	106	7	3	10	10
CHC Dharampur	13070	2482	159	554	6	28	28	46
CHC Dharlagarh	9628	2052	533	338	45	10	53	7
CHC Nalagarh	14520	4984	445	889	107	47	134	48
RH Solan	23334	4362	1773	396	425	153	506	28
CHC Total	56814	13860	1809	2342	308	134	352	141
Grand Total	**80148**	**18222**	**3582**	**2738**	**733**	**287**	**858**	**169**

Table 8.4: Comparison of known and new case detected as a result of opportunistic screening

Name of the facility	Total eligible group for screening	Total no of HTN & DM cases detected	% of cases out of eligible group	No of Known cases	% of known cases out of eligible group	No of New cases	% of new cases out of eligible group
CHC Kunihar	3404	1303	38.3%	772	22.7%	531	15.6%
CHC Syri	938	306	32.6%	187	19.9%	119	12.7%
CHC Dharampur	2482	821	33.1%	193	7.8%	628	25.3%
CHC Dharlagarh	2052	986	48.1%	631	30.8%	355	17.3%
CHC Nalagarh	4984	1670	33.5%	686	13.8%	984	19.7%
RH Solan	4362	3281	75.2%	2704	62.0%	577	13.2%
CHC Total	13860	5086	36.7%	2469	17.8%	2617	18.9%
Grand Total	**18222**	**8367**	**45.9%**	**5173**	**28.4%**	**3194**	**17.5%**

Figure 8.1: Impact of screening on detecting undiagnosed cases of hypertension and diabetes at out-patient clinics of primary care setting



Mean blood pressure level among subjects with hypertension

Among 2080 hypertension patients who attended the out-patient clinics at CHCs, a reduction of 13.1+/-13.8 mmHg was observed in systolic blood pressure, from 149.1+/-20.2 mmHg to 136.0 +/-16.0 mmHg ($t = 43.35$; $p<0.001$) at their third month of follow-up and a reduction of 6.9+/-9.3 mmHg in diastolic blood pressure, from 90.4+/- 10.9 mmHg to 83.4 +/- 7.8 mmHg ($t = 34.2$; $p<0.001$). In this group, 67% (65.4 – 68.8%) of the patients achieved blood pressure control (<140/90 mmHg) at third month of follow-up. The intra-class correlation coefficient for systolic blood pressure and diastolic blood pressure was 0.033 (0.04, excluding RH Solan) and 0.100 (0.100, excluding RH Solan), respectively, at the baseline. The follow-up rate observed at third month was 64%, as 2974 participants (out of 4644 hypertension patients) voluntarily turned up for their third month follow-up visit.

Table 8.5: Comparison of systolic blood pressure, diastolic blood pressure and fasting blood glucose at baseline and follow-up at 3 months and 6 months

	Health facilities	N	Baseline		Mean level of clinical parameters		Mean reduction in clinical parameters		t	P value
			Mean	SD	Mean	SD	Mean	SD		
SBP at 3 months of follow-up	CHCs	2080	149.1	20.2	136.0	16.0	13.1	13.8	43.35	<0.001
	CHCs & RH Solan	2974	148.4	19.3	137.5	15.7	10.9	13.1	45.46	<0.001
SBP at 6 months of follow-up	CHCs	415	148.9	18.0	135.8	13.9	13.1	16.2	16.4	<0.001
	CHCs & RH Solan	673	149.7	17.9	137.0	12.9	12.6	14.4	22.7	<0.001
DBP at 3 months of follow-up	CHCs	2076	90.4	10.9	83.4	7.8	6.9	9.3	34.2	<0.001
	CHCs & RH Solan	2970	89.4	10.3	83.8	7.7	5.6	8.6	35.6	<0.001
DBP at 6 months of follow-up	CHCs	411	91.8	11.0	84.3	7.3	7.4	10.0	15.1	<0.001
	CHCs & RH Solan	662	91.1	9.7	84.1	6.7	7.1	8.7	20.9	<0.001
FBS at 3 months of follow-up	CHCs	508	179.2	65.2	145.7	42.6	33.7	49.9	15.2	<0.001
	CHCs & RH Solan	717	171.8	62.1	145.4	40.9	26.4	49.0	14.4	<0.001
FBS at 6 months of follow-up	CHCs	47	197.7	76.5	140.9	42.1	56.8	72.3	5.3	<0.001
	CHCs & RH Solan	58	189.5	72.1	140.4	38.8	49.1	68.0	5.5	<0.001

Six months follow-up data was available for 415 patients and a reduction of 13.1 +/- 16.2 mmHg was observed in systolic blood pressure, from 148.9+/-18.0 mmHg to 135.8+/- 13.9 mmHg ($t = 16.4$; $p<0.001$), while diastolic blood pressure reduced from 91.8+/-11.0 mmHg to 84.3+/- 7.3 mmHg, with a reduction of 7.4+/- 10.0 mmHg ($t = 15.1$; $p<0.001$). In this group, 71.7% (CI: 68.3 – 75.2%) of the patients achieved blood pressure control (<140/90 mmHg) at six months of follow-up.

Impact of the intervention on glycaemic control of diabetes patients

Among diabetes patients enrolled in the study, the mean (SD) fasting glucose level reduced from baseline 179.2 +/-65.2 mg/dl to 145.7+/- 42.6 mg/dl, with a significant change of 33.7+/- 49.9 mg/dl (t= 15.2; p<0.001) at third month of follow-up. Six month follow-up data was available for 47 subjects who also had a significant reduction of 56.8+/- 72.3 mg/dl in fasting blood glucose level, from the baseline level of 197.7+/-76.5 mg/dl to 140.9+/-42.1 mg/dl (t = 5.3; p<0.001). The intra-class correlation calculated for all the six health facilities was 0.076 (0.051, when RH Solan was excluded). Further, the follow-up rate at third month was 54%, as 508 participants (out of 935 diabetes patients) voluntarily turned up for their third month follow-up visit.

8.5 Evaluation at Patient Level

To assess the impact of the intervention at patient level, IDIs were conducted with patients who were part of the intervention and had at least one follow-up visit prior to the interview. A total of 33 individuals were interviewed, comprising 18 men (54.5%; mean age: 55.7$\pm$2.9 years) and 15 women (45.5%; mean age: 53.3$\pm$3.4), chosen from five CHCs. In this group, six subjects (18.2%) had diabetes mellitus, 14 (42.4%) were experiencing hypertension and the remaining 13 (39.4%) subjects had both conditions.

8.5.1 Opinions of patients about the service delivery

All the subjects interviewed were aware that the project was specifically for the management of diabetes and hypertension patients. From the interviews, it was evident that the respondents had a high opinion about the new project and that it had gained acceptance among patients. Overall, 97% of the patients interviewed responded that they received good care from the CHCs. A 47-year-old male patient narrated his experience as below:

"This project is really helpful, and nowadays even youngsters are suffering high BP similar to older people. We are happy that a new project has come and the rush to the doctor has reduced. I wish there is more space for the NCC or a separate room for her so that we can comfortably sit and talk to NCC and take blood pressure, weight and all."

A 70-year-old female patient had the following opinion about the care she received from the CHC:

"I got good care from this hospital. When I last visited CHC, there was not much rush that day. NCC checked my BP properly. I think my BP and sugar is in control."

A 40-year-old male patient stated:

"In the OPD, there is a single doctor and other staffs are also inadequate; it is very difficult to manage such a huge number of 100-150 patients; patients may not be getting the correct treatment because of this rush. Because of the NCC, I got my BP checked and she listened to my health problems and gave me all advices".

8.5.2 Opinions of patients about Nurse Care Coordinators

The interviews revealed that the new staff – NCCs – deployed as part of the project were very much acceptable to the patients for their care. All the subjects responded that NCCs measured their blood pressure and listened to their complaints. More than four fifths (81%) of the patients received advice from an NCC and all such respondents found that advice useful. A 52-year-old male patient said:

"For the last five years, I am having hypertension and I am under treatment from this hospital. I find the new project very beneficial for patients like us. The new nurse (NCC) is

very helpful. She takes blood pressure and collects all the details. She spends time to listen me and I get good treatment from the doctor. She feeds data into her phone and she has details with her whenever I visit the CHC. The major change is that, unlike previously, the new nurse is there to provide advice on exercise, diet and medicines; but doctors are very busy as usual."

A 50-year-old female patient said:

"I got good care from the CHC. When I came last time, the nurse (NCC) took my blood pressure and told me that I have hypertension. My blood pressure was 180/100. The doctor gave me medicines and the nurse explained me how to control my blood pressure. She told me what to eat and what not to eat. I started taking less salt and oil. I am taking medicines regularly and I feel better now."

8.5.3 Patient perceptions on use of DSS

The DSS ran on a Smartphone and it was important to know how patients perceived the use of a 'mobile phone' by NCCs in the middle of conversations with them. During IDIs, patients were asked about the appropriateness of using a mobile phone in a clinic setting, their opinion of the utility of DSS and whether they felt DSS was of any use to them. Patients associated the use of a mobile phone as part of the duty of the NCC for entering data to generate patient records and a large majority of the subjects (92%) felt that recording of data was useful. A 46-year-old female patient had the following opinion on the use of DSS:

"The nurse (NCC) enters data into the phone in front of me. I think recording data is for patient care.

Similarly, a 47-year-old male patient made the following observation about the DSS:

"It is good that they keep the record in the phone. So when we come back they have my details with them".

8.5.4 Opinions of patients on the NCD OPD card

All the subjects interviewed received the NCD OPD cards during their clinic visit and 83% of them brought the NCD OPD card with them during their follow-up visits. Three quarters of the subjects (76%) thought that bringing the NCD OPD had benefits while consulting the doctor. Further, the NCC also used to write the due date of the next follow-up visit on the OPD card. A 46-year-old female patient had the following opinion on the NCD OPD card:

"Yes, I feel the card is important, because everything is written on that about my blood pressure.

Similarly a 40-year-old male patient had the following opinion:

"I bring the OPD card with me whenever I come to the CHC. There is importance to the OPD card because doctors can verify the details of our list visit; we can show it to any other doctor if we go to some other clinic."

8.5.5 Difficulties faced by patients because of the intervention

The new intervention components included opportunistic screening and history-taking of all OPD attendees aged 30 and above. These additional activities could cause discomfort to patients, affecting the acceptability of the intervention to them. Patients were asked whether such additional activities carried out by the NCC caused them discomfort. Eighty five percent of the subjects responded that measurement and questions from the NCC for the screening

and history-taking was of no discomfort to them. The remaining group was concerned about the long wait time at the CHCs associated with heavy patient load. A 40-year-old male patient said:

"I do not feel that there is wastage of time when nurse (NCC) asks a lot of questions to me; I can understand she is asking such questions for the benefit of patients."

A 47-year-old male patient also made the following observation regarding the wait time at CHC:

"I feel there is a delay in all the government hospitals because of lot of patients come here. Patients stand in queue to meet the nurse (NCC) and doctors. But the nurse (NCC) takes good care of everybody, especially older people. She gives enough time explaining the questions and takes our responses".

8.5.6 Barriers faced by patients in compliance with the intervention

During IDIs, questions were asked to discover barriers faced by the patients in complying with therapy. The narratives of the patients revealed that a third of the subjects (37.5%) thought that regular consumption of medicines was harmful for their body and 14% of the subjects said that they were irregular in taking medicines. Further, advice to the patients to be physically active was not adoptable during winter. A 47-year-old patient said:

"I stopped taking BP medicine myself; doctor did not ask me to stop the medicine; but I thought I became normal so I stopped it".

Another patient said:

"Nurse (NCC) asked me that I need to do exercise, walk more, do brisk walk or yoga. But I was unable to do any exercise in the winter; I thought I will regularly go for walk in the summer season. I tried to do yoga, but I am not able to do; I can't sit on the floor for long."

The majority of the patients treated at the CHCs were meeting the expenses of the treatment through out-of-pocket spending. Four fifths (81%) of the subjects were buying medicines from private chemist stores. In the remaining group, patients were getting medicines, partially (9%) or fully (10%), from the hospital. The mean monthly spending on medicines was rupees 1137.4 $\pm$ 1078.0. All the respondents demanded that there should be free medicines distributed to patients from the hospital and more staff and facilities added.

A 50-year-old female patient said:

"I buy medicines from the chemist shop because at the hospital pharmacy, they don't have the medicine which doctor prescribed for my illness."

A 58-year-old female patient with diabetes also had similar concern:

"From government hospital we do not get any medicine; we get only slips to buy medicines from private chemist store. The monthly expense on medicine comes around 2000 rupees, which is difficult for me to spare; but I will have to buy my medicines, because I need to live and support my family.

Similarly, a 62-year-old male patient said:

"We need more doctors and other staff here. Free medicines should be made available to all patients".

8.6 Results from the assessment of implementation determinants

8.6.1 Assessment of implementation determinants related to the socio-political context

During IDIs, multiple issues related to socio-political context were identified that were affecting the intervention. These included low education status, lack of motivation for long term intake of medicines, high cost of medicines, etc. Some of the major themes which emerged relevant to the socio-political context are described below:

Educational status: all the Medical Officers were of the opinion that the educational status of the patients was a major factor affecting compliance to medicines. A Medical Officer made the following opinion on during IDI:

"Educational status is the major factor that decides compliance, because compliance for medicine really needs awareness about the consequences of non-compliance. Patients stops medicine after two weeks and continue that way for weeks. Even educated people also behave like this. I have seen several such cases in my practice at our emergency department; patients brought there were about to collapse and surprisingly one of them was a nurse. Diabetes patients also behave similarly. The reason is that they have to take medicine every day. People get fed up. Same way, to have daily insulin injections also affects compliance."

A Block Medical Officer said:

"In diabetes patients, whatever is prescribed it has good compliance. One thing I observed was, if people are regular on medicines, they may not control food, thinking that medicine will take care of their illness."

A NCC had the following opinion on difficulties in counselling:

"Counselling poor and illiterate and old age is difficult and we need to repeat the messages to them. Even then I find only 25% of the patients comply to the drugs that we suggest, because we have lot of poor patients from the labour class and they will take a lot of time to understand the consequences of non-compliance"

Limitations of lifestyle advice: in the IDIs, we explored the perceived effectiveness of lifestyle advice by the healthcare team in terms of patients practicing the advice. The NCCs were of the opinion that educating people from a low socio-economic group was difficult, particularly in convincing them about reducing salt and ghee (fats). They found that longer or multiple sessions of counselling were required for the poor. Further, it was hard for people to quit tobacco, even after multiple advice. Further, convincing people of the importance of lifelong compliance to medicines was another challenge. It was common to find patients stopping medication after continuous intake for two weeks, when they found symptoms were relieved. A NCC narrated her experience with patients:

"*Patients listen to our advice. However, low education group often think that hypertension gets cured in one to two weeks of medication and then they stop it. So each time I need to explain them and spend more time with them."*

Similarly another, NCC said:

"Not all patients follow the advice, particularly the poor. We need to repeatedly convince them on salt and tobacco. Reducing ghee is difficult for many of the patients. Some patients stop taking medications thinking that it harms their health and I try to convince the harms of stopping medicines"

A Block Medical Officer said:

"I find medicines have good compliance and 90% of patients follow it. But lifestyle modification is difficult. One may control alcohol, food and, to a certain extent, exercise as well, but quitting tobacco is very difficult. There is no doubt that NCC has to counsel patients; but there are some difficulties for patients in changing their lifestyle. For example, housewives engage in household chores and they won't have any time for regular exercises. So is very difficult to practice that message by such patients. Similarly, partying has become a routine in these days and abstaining or limiting food from such occasions is difficult."

Language barriers: in Himachal Pradesh, aside from modern Hindi, several local tribal dialects are spoken which are difficult for outsiders to comprehend. The NCCs, although belonging to the same state, had difficulties in communicating with patients belonging to tribal groups. A NCC had the following opinion about language barriers:

"There is a language difficulty. Some of the people coming here speak local tribal language and I speak Hindi. In such situations, both of us won't be able to follow each other".

8.6.2 Assessment of implementation determinants related to the organisation

Nurses, deployed as Care Coordinators at the OPD, form additional manpower for the project. The challenges faced by nurses, as narrated by them, provide insights into operational challenges of the project at the organisational level.

Lack of space: in five of the OPD clinics, the doctors were sharing their consulting room space with the NCCs, due to space crunch at the hospital. As a result, there was very limited space for the NCC to conduct patient evaluation, counselling and keep equipment. Whereas

in three other clinics, the NCCs were sitting in a room separate from that of the doctors. In the former group, the NCCs were doing additional work at the insistence of the doctor, such as collecting details of illness from non-hypertension/non-diabetes patients for them and explaining drug prescriptions to patients. Although it reduced the workload of the doctors, it also resulted in less time for NCCs to attend to hypertension/diabetes patients. This problem was most notable in two clinics having heavy patient load at the RH Solan, which was run by specialist doctors. In these two clinics, the NCCs were hurriedly disposing patients because the doctors wanted to do so, otherwise they would not finish examining the patients that were lined-up. During IDI, a NCC said:

"Sir, the main issue is the crowded OPD room. It would have been much better if we have some more space to sit comfortably and do the measurements and explain the patients about the diseases they have".

Another NCC said:

"Major problem we have is the heavy patient load. Throughout the day we are engaged. We are not able to do screening also. There are multiple measurements, history-taking and counselling and data-feeding to the phone. We are not able to complete everything fully when the number of patients exceeds fifty."]

Patient priorities: though known cases of hypertension and diabetes were receptive to NCC queries, screening questions to people with undiagnosed status were often not received well, because their visit to the facility was to seek care for other ailments. In such situations, the NCCs spent additional time explaining the reasons for asking questions and motivated them for their cooperation. A NCC had the following opinion on patient priorities:

"Known patients are very cooperative. While screening, when we ask questions to people who came to the hospital for other disease conditions may not understand why we are asking questions on HTN/DM and their mobile number. Then we need to explain them the reasons and get their cooperation."

Insufficient manpower: at specialist clinics of RH Solan, there were a high number of hypertension/diabetes patients attending, because of this screening activities were not able to be included as additional manpower was required. During IDI, a NCC said:

"Because we have 70-80 DM/HTN patients in a day, we are unable to do screening because we have multiple tasks of measuring BP, height, weight and recording data in phone in the short time we have. We would need more staff to manage our OPD if we need to do screening also".

The educational status of patients was an important factor that determined the speed with which patient counselling could be done. In five of the clinics where NCCs sat in the same room as the physician, the NCCs were not able to spend enough time either conducting counselling sessions at a slow pace or doing group sessions, because the doctors wanted to dispose patients quickly to complete the OPDs in time. A NCC said:

"Some people are more concerned about their health and they follow our advice, but some patients may not follow the advices quickly. Then we have to spend time and have to repeat everything slowly to make them understand. We are not able to do that every time, because patients are waiting outside and the doctor moves very quickly."

Availability of drugs: during the post-intervention IDIs, the perceptions of the healthcare team were explored to assess how the availability of drugs at the health facility was affecting the implementation of the intervention. The Medical Officers were of the opinion that drug

availability did not change during the intervention phase and was similar to the pre-intervention phase. The availability of medicines was not uniform across all the health facilities and there were mismatches in the availability of drugs with the guideline and the quantity supplied. Hence, most patients were meeting the expense of the drugs as out-of-pocket expenditure similar to the pre-intervention phase. A Medical Officer had the following opinion on drug supply at the CHCs:

"Supply of medicines is not enough in the CHC and that is a major issue. Most patients buy medicines from the close by chemist store….

…….. The new clinical guideline is very useful and it is very straightforward; but first line medications like ACE-I and ARBs are expensive and poor can't afford it unless we have it in our supply; then we go for Amlodipine which is cheaper. If you have provision for drug supply, we could completely implement it."

A NCC had the following opinion on drug supply at CHC:

"The medicine supply is erratic. Two weeks back supply arrived and we have Enalapril here, but not much diabetes medicines. I used to get complaints from patients that nothing is available here."

A Medical Officer stated during IDI:

"We have only Atenolol in the supply; we don't have other medicines. We prescribe medicines to buy from outside only. Although our BMO make intent to the district headquarters, drug supply is erratic".

A NCC said:

"All medicines are not available; only amlodipine was available, but now nothing in supply; for diabetes patients metformin is available. Patients buy of the drugs from outside, especially combination drugs."

All the specialist Medical Officers expressed their concern that combination preparations, newer drugs and insulin were not available in the government supply. Hence poor patients were unable to afford such medication, thereby affecting compliance. A specialist physician said:

"The drugs supply is also not enough, particular combination medicines which we usually prescribe. Unless we address these shortcomings, we can't improve the care from here. What we observe is the difficulty for patients to continue on these lifelong medicines. The drugs are expensive and here we treat complicated cases and cost of care is not affordable to the poor. That is the major challenge."

In order to get a clear picture of the availability of medicines at the health facilities, the details of drugs supply to the hospital were taken from the records (see Table 8.6) for the period Dec 2012 – June 2013. Information on anti-hypertensive medications, oral hypoglycaemic agents, insulin, Aspirin and Inj.Streptokinase, which were listed as part of the essential medicine supply, were collected. The overall supply of drugs to these facilities during the above period was 83,800 tablets. The distribution was skewed in such a way that two hospitals (CHC Dharampur and RH Solan) got 60% of the supply, while the remaining portion was distributed to four hospitals. The RH Solan, which had specialist clinics serving referral patients, was supplied Atenolol alone, while no oral hypoglycaemic agents or insulin

was supplied. During the entire six months, CHCs Kunihar and Nalagarh were not supplied any of the anti-hypertensive medications and none of the facilities received sulphonylurea class medications or insulin for diabetes management.

Table 8.6: Supply of drugs to 5 CHCs and RH Solan during Dec 2012 to Jun 2013

No	Name of the drug	CHC Kunihar	CHC Nalagarh	CHC Syri	CHC Dharlagarh	CHC Dharampur	RH Solan	Total
1	Tab. Aspirin	-	-	-	-	-	-	**0**
2	Tab. Atenolol	-	-	3500	1000	5400	28000	**37900**
3	Tab. Enalapril	-	-	-	1000	11200	-	**12200**
4	Tab. Amlodipine	-	-	2000	1000	-	-	**3000**
5	Tab. Hydrochlorothiazide	-	-	-	-	-	-	**0**
6	Tab .Atorvastatin	-	-	-	-	-	-	**0**
7	Tab. Metformin	11200	11200	3000	-	5300	-	**30700**
8	Tab. Glipizide	-	-	-	-	-	-	**0**
9	Tab. Glibenclamide	-	-	-	-	-	-	**0**
10	Tab. Ramipril	-	-	-	-	-	-	**0**
11	Inj. Insulin	-	-	-	-	-	-	**0**
12	Inj. Streptokinase	-	-	-	-	-	-	**0**
	Total	**11200**	**11200**	**8500**	**3000**	**21900**	**28000**	**83800**

8.6.3 Assessment of implementation determinants related to healthcare team members

Traditionally, nurses are posted for indoor duties, particularly in the in-patient wards. The functions of NCCs differ from the duties of ordinary nurses in several ways. They are posted in OPDs, do patient evaluation, use DSS, conduct patient counselling and make phone calls to ensure patient follow-up visits, and they do not have night-duties. Such a nature of work invited comments from other nurses in the hospital. One of the NCC said:

"Some of the nurses tell me that I am wasting my time here and I should go and work elsewhere, because it is not the job of a nurse. I don't know what to tell them. I am happy that I don't have night duty."

Similarly, another NCC stated:

"Other staff are helpful and doctors also very cooperative. But nurses tell us that I need to be posted in the wards instead of OPD. The main reason for their comment is that we don't have night duty!"

NCCs were a new cadre at the hospital to deliver hypertension and diabetes care, as part of the intervention. The acceptance of NCCs by the patients was one of the key factors that determined the success of the intervention. In the IDIs with NCCs, we explored their perceived acceptance by patients. The NCCs felt that patients had identified them as a dedicated care giver for hypertension and diabetes. In addition, patients had also started directly approaching the NCCs for measuring their blood pressure, and for advice on drugs, lab reports and diet. The confidence they enjoy from the patients is evident from their words. One of the NCC said:

"Now we have been in this hospital for more than six months. Now patients know we are for HTN and DM. So patients come directly to us and ask us to clear their doubts about medicines, diet and what test to be done, how to prepare for tests and follow-up visits."

Another NCC stated:

"Patients respond very positively. A change I have observed is that nowadays, the regular patients come to us directly and give their report and ask for our advice".

Similarly, another NCC said:

"Now patients come and ask me questions regarding their health and take advice on drugs, what to take, what not to take. Some people even think I am doctor."

8.6.4 Assessment of implementation determinants related to attributes of the intervention

The uptake of an intervention is mainly influenced by five key attributes among several attributes of an intervention. These include relative advantage, compatibility, complexity, trialability and observability. Results from assessment of these determinants are described below:

Relative advantage of the new intervention was assessed during the post-intervention IDIs with the Medical Officers while exploring their opinion about the impact of the project on service delivery at the health facility. All the Medical Officers were of the opinion that the new project had resulted in improved service delivery from the health facility, increasing the detection of unknown cases and higher patient compliance to management and follow-up.
The major reason cited by the Medical Officers for the relative advantage was the dedicated role of NCCs in service delivery for hypertension and diabetes care.

Compatibility: the appropriateness of NCCs conducting screening and clinical examination of patients and the use of Smartphone-based DSS for generating patient management plans was discussed during in-depth interviews, in order to assess the compatibility of the intervention. The Medical Officers found the facilitator role of NCCs and the use of DSS-based clinical management guidelines highly helpful for them and consistent with the existing work procedures of the CHCs. In addition, none of the Medical Officers were of the opinion that any component of the interventions was against their personal beliefs or values of the organisation. However, specialist physicians at RH Solan felt that the clinical management guideline was inadequate for their use and wanted an advanced version to treat complicated cases. Compatibility of the intervention was also found to be dependent on training. Newly-

posted Medical Officers, who were not familiar with the intervention, would not allow the NCC to conduct opportunistic screening or accept the DSS-based management plan. However, their attitude changed after they underwent training on the intervention.

Complexity of the intervention was assessed by asking the Medical Officers whether the screening and the new workflow adopted as part of the intervention was causing additional burden to their work, and whether the new clinical management guideline was easy to follow. All the Medical Officers had favourable opinions on the changes, because the additional workload was mostly borne by the NCC. Further, the new clinical management guideline made patient evaluation more structured and easy for the Medical Officers to decide the management. The NCCs were asked about the perceived complexity of the DSS and their response was that the iterations of the DSS with their feedback made it less complex and user friendly.

Trialability: the willingness of the healthcare team at five CHCs and RH Solan to pilot the intervention for eight months demonstrated the trialability of the intervention. In addition, during the IDIs, all the Medical Officers expressed their strong desire to continue the project in their clinics, which also underscores the trialability of the intervention.

Observability: during IDIs, the Medical Officers expressed the following perceived benefits from the intervention: 1) assistance from the NCC in history-taking, therapeutic counselling, measurement of blood pressure and anthropometry; 2) a systematic patient evaluation facilitated by the NCC and generation of clinical management plan with the help of DSS; 3) generation of a patient record that helped in follow-up visits to assess patient achieving treatment targets. That the Medical Officers felt these to be observable results demonstrated

the observability of the intervention.

Characteristics of DSS and Hardware: although the DSS was carefully developed and the Smartphone was carefully chosen, some of their characteristics were found to be affecting the implementation of the intervention. During their eight months of tenure, the NCCs accumulated a sizable number of health records in the DSS. In many clinics, there were several patients with the same name. Hence, fetching records of previous visits by such patients from the DSS turned out to be time-consuming. The NCCs felt that the small screen size of Smartphones was a limitation and wanted a tablet or laptop, which have larger screen size, to view and edit a greater number of health records on a single screen and reduce time spent on DSS. This limitation was a result from the design flaw of the DSS and the smaller screen size of the Smartphones. One of the NCCs had the following opinion on DSS:

One problem I face is that several of the patients have same name and now I can't recognize their record. If you could make a change in software in such a way the list of people having same name appear as we enter a name, then that would help us in quickly identifying existing entries. Similarly, if you could give us a tablet or laptop we could easily do the data entry and view it properly."

8.7. **Results from evaluation on continuation of the project**

Continuation of the project at the CHCs and expanding it to other facilities was one of the key questions explored with the Medical Officers during in-depth interviews. In addition, the views of all the Block Medical Officers were also sought for their feedback on expanding the project to other CHCs. It was found that all the Medical Officers and Block Medical Officers

were in favour of continuing the project at their CHCs. A Block Medical Officer said:

"Definitely; If possible, this project should be extended to other CHCs as well. My only suggestion is to have provision for including patients below the age of 30 as well."

The specialist physicians at RH Solan were also in favour of continuing the project. They wanted modification in the DSS to include additional medicines to suit their prescription patterns and additional NCCs to meet heavy patient load at the specialist clinics of RH Solan. A specialist physician made the following suggestions during IDI:

"Your project should be expanded to all CHCs to benefit patients. For RH Solan, I need at least one more NCC so that we can comfortably attend all the patients. The guidelines and software needs modification, so that specialist physicians can also use it in hospitals like this".

8.7.1 Extent to which the intervention became routine and part of the everyday culture and norms of the organisation

The evaluation of the intervention revealed that the intervention was well-received at all the health facilities involved. This became evident during post intervention in-depth interviews with the Medical Officers at the CHCs, who enquired how long the project would continue and whether it was going to be extended to the entire state by the state government. Further, the intervention activities and the changed workflow have continued at all the health facilities without any deviation since the beginning. Encouraged by the results from the intervention, the CHCs are taking the intervention to the next level by starting a community outreach programme. The outreach programme commenced with a baseline survey in selected sub-centre areas to determine the prevalence of hypertension and diabetes in the community

through trained community health workers. People identified ‘at risk’ are being linked to the respective CHCs by the community health workers for care and follow-up.

With regard to intervention beneficiaries, patients also started identifying NCCs as a dedicated care provider for hypertension and diabetes from the health facility. All the NCCs find several patients approaching them directly to measure their blood pressure and to seek advice on drugs and lifestyle changes. A NCC stated:

“Now patients come and ask me questions regarding their health and take advice on drugs, what to take, what not to take. Some people even think I am doctor.”

8.7.2 Suggestions from the Medical Officers to improve the intervention

Suggestions were sought from the Medical Officers for improving the delivery of the intervention. An important suggestion was to display a clinical management algorithm chart at the OPD as a ready-reckoner for the Medical Officers. Since transfer and postings of Medical Officers can happen frequently, new appointees may not be aware of the project and might deviate from the intervention until they are trained. The Medical Officers were of the opinion that a poster with official logos, displayed prominently at the OPD, would ensure that the new doctors follow the guidelines to a certain extent. Another suggestion was on scheduling one or two CMEs a year for Medical Officers at CHCs to ensure reinforcement of disease management to existing staff, as well as for providing exposure to new staff about the intervention. A Block Medical Officer made the following suggestions during IDIs to improve the intervention:

“I think there is a need for regular training for the doctors. If you could make a poster

displaying the guideline, that would be very useful, because transfer and posting of doctors can occur in-between and it's better to have a the guideline to be followed displayed prominently."

Doctors also use certain ways to improve compliance. These include starting drugs at a low dose to minimise side effects and slowly increasing the dose and the use of cheaper drugs with fewer side-effects, such as Amlodipine, to ensure compliance. During IDIs, a specialist physician narrated some of the strategies he followed:

"In hypertension patients, I find Amlodipine is having good compliance as it is cheaper and doesn't have much side effects; it is there in our supply as well. In diabetes patients, I prescribe Glimepiride and Metformin, which are also cheaper and are part of drug supply. I start with a lower dose and, if it is tolerated well, then increase the dose. If there are problems, I will switch the medicine and try combinations. This way compliance can be ensured."

8.7.3 Medical Officers' suggestions to improve the services of NCCs

Feedback from the Medical Officers was sought to improve the services of the NCCs. The doctors were of the opinion that the NCCs have to be accommodated in the same room as the doctors. They felt that the screen size of Smartphones was inadequate for running and using DSS and, thus, suggested switching to tablet or laptop for running the DSS. A Medical Officer had the following opinion:

"The doctor and the NCC has to sit in the same room; instead of phone a tablet or computer would be better and that would help more in patient management and we can use DSS more

effectively; unfortunately, we don't have enough space to accommodate NCC in the consulting room."

Similarly, a specialist physician said:

"The major deficiency I see is that these NCCs don't have a proper place to sit. If sufficient space can be given them with all the provision for weight, height, BP measurement and doing patient counselling, that would improve the care a lot."

Another specialist physician said:

"Probably you should give these girls a notebook or tablet, because it is difficult for them to feed data into phone from large number of patients. There is too much strain to the eyes. After two years, she will be wearing big spectacles. Nowadays tablets are very cheap. You will get it for 12000, 15000 rupees. That would be a better option."

All the Medical Officers wanted glucometer and strips given to clinics, citing the reason that diabetes patients would benefit immensely from getting quick results from which Medical Officers could make quick clinical decisions, thereby reducing patient waiting time. Further, they also suggested making pamphlets for distributing to patients as part of behaviour change advice. A Medical Officer made the following suggestion:

"A suggestion I have is that, if you can provide glucometers to NCC, diabetes management will be much easier for us. Secondly, instead of Smartphone, if you can provide laptop or tablet that would be easy for the NCC to use……..

…… They would also benefit if you could organize refresher training for them, particularly lifestyle counselling. Can you also print pamphlets on diet for distributing to patients; I think that would be very helpful."

An important suggestion made by a Block Medical Officer was to organise weekly education sessions for patients on self-care of non-communicable diseases at the hospital, with sufficient publicity made at the community level through health workers. Further, he also stressed the importance of training NCCs to develop their counselling skills to guide the patients on lifestyle changes. A Block Medical Officer said:

"NCC could organize weekly NCD awareness sessions at the hospital. Doctors can also take classes. We also need to distribute printed materials to patients on lifestyle modification. We also need to make sure that the staff are passing same messages to the patients and not conflicting messages; this is not only during awareness sessions, but also during treating individual patient by the doctors and NCCs." ……..

……NCCs need to be trained to develop good counselling skills so that patients understand and practice their messages. Lifestyle modification depends on how good their counselling skills are.

8.7.4 Facilitators to be addressed to improve the delivery of the intervention

During post-intervention IDI, questions were asked to understand what additional changes (facilitators) are needed to improve the delivery of the intervention. It appeared that the system level barriers, such as insufficient number of doctors, inadequate supply of medicines and lab facilities, remained the same as in the pre-intervention period. However, the healthcare team (both doctors and NCCs) identified additional requirements to improve the care delivery. The identified requirements are listed below in order of priority:

1. *Provision of adequate work space for NCCs* to keep their equipment and ensure adequate privacy while taking patient history and measurements.
2. *Replacing Smartphones with tablets to run the DSS.* Smartphones, though very

convenient to carry because of their smaller size, have limitations because of its smaller screen size. On the other hand, tablets offer bigger screen size, enabling the display of a larger number data elements of DSS, thereby reducing the need for scrolling down and time spent on the application, Additionally, they are easier to incorporate key functions, such as search options to retrieve old patient records. Because of these reasons, a tablet-based DSS was suggested as a major requirement to improve the intervention.

3. *Provision of glucometers and strips at the OPD* was another suggestion to reduce waiting time for diabetes patients, as well as for conducting screening at the OPD.
4. *Distribution of pamphlets for patient education* by CHCs during counselling session to improve patient awareness on lifestyle change and compliance to medicines
5. *Regular CME for doctors and refresher training for NCCs* to ensure that the healthcare team is updated about recent advances in medical care and to bring relevant changes in their practices.
6. *New clinical management guideline for specialist physicians* who cater to complicated cases of hypertension and diabetes
7. *Additional NCCs* for OPDs that exceed the threshold of 25 hypertension/diabetes patients a day or whose overall patient load exceeds 60 a day to ensure that patient evaluation and counselling services are delivered as planned.
8. *Improving facilities* such as provision of comfortable seating space in the patient waiting areas to reduce stress on patients who usually face a long waiting time

8.8 Discussion

The pilot implementation of the mPower Heart intervention provided valuable insights for implementing an intervention for hypertension and diabetes care at primary care setting in

Himachal Pradesh. The pilot intervention demonstrated the feasibility of integrating hypertension and diabetes care into the daily routine of CHCs with the deployment of trained nurses, supervised by doctors. The healthcare team - particularly the Medical Officers - expressed high degree of satisfaction with the intervention. Further, greater compliance of evidence-based clinical management guidelines and favourable health outcomes, such as reduction of blood pressure and blood glucose level among patients, were also observed. The intervention also gained high acceptance among patients. The scalability of the intervention was also demonstrated and the current design of the intervention merits moving to the next phase of a randomised control trial for assessing its effectiveness on process and health outcomes.

The pilot intervention highlighted a major gap in hypertension and diabetes care at primary care in India by detecting large number of undiagnosed cases of hypertension and diabetes through opportunistic screening. Detection of large number of undiagnosed cases – to the tune of 20% out of the eligible thirty plus age group - during screening was a major finding from the pilot intervention. The high rate of undiagnosed cases of hypertension and diabetes was consistent with other community based study reports from India [35, 169, 170]. However, this finding is the first report from India from a six month long opportunistic screening carried out in primary care setting. This finding echoes the call for greater attention to develop and implement interventions for hypertension and diabetes in India [25, 26].

The primary care system in Himachal Pradesh faces acute shortage of manpower [168]. Hence, without additional manpower it would have been impossible to pilot this intervention. The multiple tasks undertaken by Nurse Care Coordinators - such as opportunistic screening, history-taking, clinical measurements, running the Smartphone decision-support tool and

patient counselling – as part of this intervention could only be delivered through additional manpower, a fact very much appreciated by the Medical Officers. Further, it was also evident that the additional manpower – the Nurse Care Coordinator - cannot be dedicated simply for the provision of diabetes and hypertension care at out-patient clinics, as the Medical Officers were insisting the nurses assist them in caring for other groups of patients as well. Because of the greater authority that Medical Officers enjoy over other cadre of staff, the nurses could not resist such instructions from the doctors and this led to dilution of the focus of the intervention, particularly in out-patient clinics which serve a large number of patients. Hence, additional nurses would be required for out-patient clinics that cater to more than sixty patients a day; this finding has implications for scaling-up the intervention in a programme mode.

From an implementation point of view, it can be inferred that the Smartphone DSS had a major role in improving process of care. The DSS component of the intervention resulted in patient evaluation conducted in a systematic manner and aided in use of clinical management guidelines. It also benefited in capacity building of additional manpower – Nurse Care Coordinator – for hypertension/diabetes care. The availability of health records in electronic form was another advantage that helped in assessing hypertension/glycaemic control in patients. The incorporation of the NCD OPD card in the intervention also improved the process of care. Since the patients were given the NCD OPD card, which recorded the medicine and follow-up visits along with their clinical parameters, this had an impact on greater compliance to medicines and follow-up visits, as evident from interviews with patients and Medical Officers. Such learning from the piloting of the intervention has enriched the design of the intervention.

Although the use of a printer to prepare the NCD OPD card was considered at the beginning of the pilot, it was abandoned due to the cost of recurring expenses on supplies, requirement of power and other technical challenges in connecting Smartphones with a printer. However, if the health system could accommodate the cost of the hardware and supplies, a printer would reduce of manual errors and time spent in preparing the NCD OPD card. Further, in most OPDs, due to non-availability of stadiometers, markings made on the walls were used as a proxy for stadiometers. A new stadiometer was supplied to all OPDs as part of the project. Many of the female NCCs were experiencing difficulties in measuring the height of taller men at the clinic. We found that certain modifications to the equipment, such as combining the stadiometer and weighing machine, would save time and effort spend by the healthcare team for physical measurements. These bottlenecks point towards the tremendous scope for developing a hardware device for out-patient clinics in India which combines the features of measuring blood pressure, height and weight with the capability of connecting with a Smartphones and printing the outputs from the DSS. This method would be a solution for addressing the difficulty of short individuals who try to measure height of taller individuals and in reducing the chances of error while transferring data to electronic systems.

Even though the intervention made hypertension and diabetes care delivery more systematic – through structured patient evaluation, use of clinical management guideline and counselling – insufficient supply of medicines at the CHCs had an impact on the practice of evidence-based clinical management guidelines. Poor socio-economic groups could be most vulnerable to such a barrier in receiving evidence-based care. Hence, ensuring drug supply at CHCs would be an important measure to address this barrier. The shortage of supply, documented at the baseline, did not improve during the intervention phase either. The shortage of supply during the intervention phase was to the tune of 92%, assuming that the 5086 patients

identified required at least one medication a day and that the overall supply was just 83,800 tablets (anti-hypertensive and oral hypoglycaemic agents together) against the required number of 1,068,060 tablets for seven months. Moreover, among anti-hypertensive medications, supply of beta-blocker (atenolol) - which is currently recommended only for subjects who had a CVD event-was more than double (37900) than that of the two front line medications (ACE-inhibitors and calcium channel blockers) together (15200). Further, none of the facilities received sulphonylurea class medications or insulin for diabetes management during the entire six months of intervention. Due to insufficient availability of medicines, most patients were relying on out-of-pocket spending for medicines, which could lead to poor compliance and lower number of follow-up visits in the long run. The importance of ensuring drug supply, at least to the poor socio-economic group, was also evident from the patient interviews, as many of the patients expressed the financial burden on them from taking lifelong chronic care medications, which has a bearing on compliance to medications. Furthermore, 81% of the participants interviewed relied solely on out-of-pocket spending for purchasing medicines, which is similar to the estimates of India (86%) for the years 2011 on out-of pocket spending on healthcare [171].

The high degree of acceptance of the intervention among patients was promising. It can be inferred from the response of the patients that the 'human factor', i.e. the Nurse Care Coordinator, had a major role in the delivery of the intervention, resulting in greater acceptance of the intervention. The choice of 'nurses' as the additional manpower seemed to have worked in two ways. Firstly, their training background perfectly fits them for a clinical setting with little additional orientation. Secondly, the nurses demonstrated high acceptance from patients as a care coordinator because of their natural role in a clinical setting. These advantages may not be possible with other heath cadre, such as pharmacists or health

workers. Furthermore, the comparatively easier access for patients to a Nurse Care Coordinator than a doctor to explain their health concerns and more time available with the Nurse Care Coordinator to listen and counsel patients were important factors that resulted in the high acceptance of the intervention among patients.

While piloting, the new intervention was found to be vulnerable to certain barriers, such as insufficient manpower, laboratory facilities, drug supply and space constraints at the CHCs. The gross insufficient capacity of the health system is linked to larger macro level issues. Insufficient investment in training manpower, their recruitment, building facilities and supplies to meet the needs of the growing and greying population have led to such capacity gaps in India. Therefore, addressing these capacity gaps of the health system is vital, while adding new interventions and subsequent scaling–up into programme mode.

Even with the above described limitations, the members of the healthcare team felt that intervention had improved care at the health facilities, demonstrating its *'observability'* as well as its *'relative advantage'* over the routine care during the pre-project period. The intervention was *'compatible',* as it easily merged with the ongoing work procedures and was less *'complex'* to adopt by the healthcare team. Further, the implementation of the pilot demonstrated that the newly developed intervention could be subjected to trial, demonstrating its *'trialability'*. These characteristics are essential for newly developed interventions to pass to the next stage of a randomised control trial. In addition, the enthusiasm from the stakeholders, such Medical Officers and the Block Medical Officers, to continue implementing the intervention is suggestive of scalability of the intervention, provided the capacity of the health system is also adequately enhanced.

Although the evaluation of piloting of the intervention provides encouraging results, there were limitations to the conclusions due to the limited number of CHCs involved in the study. The piloting of the intervention was confined to six outpatient clinics from five CHCs in Himachal Pradesh. Further, most of the evaluation focused on the six Medical Officers who were assigned to implementing the intervention, two Block Medical Officers, eight Nurse Care Coordinators and two specialist physicians running the specialist clinics at RH Solan. This limited number of participants may not actually represent the entire CHC-based workforce in the state. There were resource constraints to expanding the pilot intervention in a greater number of facilities and conducting evaluation. Further, it was impossible to include participants in the evaluation process who were not part of the implementation of the pilot. A second limitation might be that the eight Nurse Care Coordinators, being employees of the mPower Heart Project, might only present a favourable picture of their views during the interviews. However, their views were similar to those of the Medical Officers, who were not bound to provide biased opinion during evaluation because they were employees of the government and not answerable to the project evaluation team.

Another limitation was the difficulty in assessing the precise impact of the intervention at the level of patients. Patients consented could be more likely to be positively disposed toward the ongoing intervention resulting in selection bias. In addition, patients often believe the research team members who conducted the interview was part of the intervention team or from the health department. This assumption could lead to social desirability bias when a respondent provides an answer which is more socially acceptable and pleasant side of their experiences than his / her true attitude or unpleasant experiences.

8.9 Conclusion

The piloting of the mPower Heart Project demonstrated that a Smartphone-enabled hypertension and diabetes intervention package is feasible. The scalability of the intervention is contingent upon improving the capacity of the health facilities with additional resources such as manpower, supply of drugs and laboratory facilities. The developed intervention package merits further evaluation in a randomised control trial linking the intervention with process as well as health outcomes.

SECTION D

Outline of the section

Discussion of the results from this research work is presented in this section, which has two chapters (Chapter 9 & 10). Chapter 9 focuses on discussion of the results while Chapter 10 encompasses conclusions derived from this research work, recommendations to the policy makers and descriptions on outcomes of the mPower Heart Project.

CHAPTER 9: Discussion

9.1 Introduction

In this research, an intervention for hypertension and diabetes for primary care setting was developed for India, and the implementation of the intervention was subsequently evaluated in five Community Health Centres, using a mixed methods approach.

Reflections on the main findings from the study are presented in this chapter. It revolves around three main themes: 1) the experiences during the process of design of the intervention; 2) the findings on the evaluation of the pilot intervention, which can now proceed to a definite controlled trial (phase-3) to evaluate its effectiveness on clinical outcomes; and 3) implication of the findings in the Indian context and their importance.

9.2 Reflection on the findings on the adoption of the intervention

This research work is the first attempt in India to develop an intervention for hypertension and diabetes for primary care facilities in India and was primarily carried out in six out-patient clinics of CHCs and also extended to two specialist clinics catering to referral patients at Regional Hospital Solan, in the Solan District of Himachal Pradesh, India. The development of the intervention was carried out with input from the healthcare team of the CHCs, while implementation was carried out in a formative evaluation design. This research work coincided with an era marked by greater recognition from India's central and state governments of chronic diseases control programmes in India. This was evident from the 2008 launch of the National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular diseases and Stroke (NPCDCS) by the central government in a pilot mode in

10 districts and the subsequent proposal to expand the programme to all Indian districts by 2017. Preliminary work to implement the NPCDCS in three districts of Himachal Pradesh is currently underway. Due to the current enthusiasm for chronic disease control programmes, the adoption of the intervention went relatively smoothly at all levels. The higher functionaries at the health department were highly receptive to the new initiative. However, bureaucratic tangles considerably delayed the adoption stage of the intervention for a period of four months. The delays in the bureaucratic system actually stemmed from the fact that the administration of the Indian health care system is highly procedural and rigidly hierarchical, with a top-down approach to decision-making and implementation. Although there were initial delays, the permission we received from the state authorities, and subsequent concurrence from the district health administration, along with government orders, formalised the implementation of the project at the health facilities.

The hierarchy in various cadres of the health system is an important factor to be considered when planning interventions for its better adoption in the health system. In order to avoid any potential conflicts with the power relationships within the healthcare organisation, the new project's staff – the Nurse Care Coordinators – were kept under the supervision of the Medical Officer of their respective clinics who, in turn, reported to the Block Medical Officers. The shortage of nurses posted at the hospitals was another concern. We were initially warned that the BMOs could instruct the nurses to attend wards if they felt there was a shortage of nurses due to leave or transfers. To avoid such situations, we were able to secure strict instruction to the CHCs from the Chief Medical Officer to dedicate the NCCs only to OPDs. Further, the NCCs were given uniforms similar to that of nursing staff to ensure that their identity was similar to other nursing staff and that they were not labelled as 'project staff'. The formal reinforcement by higher management and the additional measures

helped in a smooth adoption of the intervention by the healthcare team and its integration into the organisational policies.

The experience from designing the intervention suggests that health interventions need to factor in such innate context characteristics to ensure better adoption. Considerable attention needs to be paid to securing support from the highest level of authorities to ensure the cooperation and smooth implementation of any new interventions in the health system. During initial discussions for permissions, our suggestion to include a control arm for better comparison did not find favour with the administrators, simply due to the fact that the political leadership was wary of an intervention that offered nothing in particular to the public in the control health facilities. Hence, researchers need to be sensitive to the realities of the socio-political context in which the interventions are to be developed and implemented. This was also reinforced at the healthcare team level when a particular hospital administrator gave permission for needs assessment and implementation of the intervention only after written government orders were handed to him.

The adoption of the intervention was relatively smooth because of the absence of an ongoing programme for hypertension/diabetes in the district. Hence, the administration and the healthcare team were open to a new intervention because it addressed a perceived need. Further, it also offered additional manpower, a new clinical management guideline and decision-support tools that relied on best practice. Adoption would have been difficult if the new intervention had been superimposed onto an existing programme.

9.3 Reflection on the implementation of the intervention

The intervention went through several challenges during its implementation. It is worth discussing them to highlight potential challenges that might arise while attempting the intervention in a control trial or in developing interventions of similar nature in similar settings in future.

The implementation of the intervention in the CHCs exposed larger systemic deficiencies of the Himachal Pradesh health system, which is no different from most of the other state health systems. Inadequate manpower, insufficient drug supply and inadequate lab facilities severely affect the capacity of the health system to even provide routine health programmes for infectious diseases and maternal and child health. The health facility assessment exercise clearly demonstrated that the infrastructure at the government health facilities in Himachal Pradesh is yet to meet the Indian Public Health Standards issued by the Government of India in 2007. According to the statistics of the National Rural Health Mission, the shortage of specialists at CHCs and PHCs combined was to the tune of 98% and that of pharmacists was 33% [165]. Two thirds of the positions for laboratory technicians (64%) and nurses (63%) were lying vacant [165]. Further, the overcrowded facilities did not provide sufficient time for the physicians to conduct a detailed patient evaluation or provide privacy for patients. Hence, it is conclusive that, unless the health system invests in developing its capacity, any new addition of chronic disease control interventions/programs would fail in the current scenario.

The core activities of the intervention were opportunistic screening and guideline-based clinical management. Opportunistic screening was made fully integrated into the routine care because it was purely in the domain of the Nurse Care Coordinator. However, ensuring

compliance to guideline-based practice was most challenging because it was in the domain of the Medical Officers. We found an overall 73% compliance to guidelines at the OPDs of CHCs, with only two out of the six CHC OPD clinics with less than 50% compliance. The reason for low compliance to guidelines in two CHC OPDs during the assessment was due to two new Medical Officers being posted at the OPDs and who had yet to receive training on the intervention. However, it indirectly provides an estimate on the change in practice pattern that a new clinical guideline can bring about at CHCs. The specialist OPDs at RH Solan were an exception in compliance to clinical management guidelines. The variation in compliance to guidelines at RH Solan needs to be explained differently. The specialist clinics differed from the rest of the OPDs in the profile of the patients and the profile and complications of the disease conditions. Hence, the specialist physician's practice differed from Medical Officers practicing in OPDs of CHCs. However, the pressure on the specialist physicians to be 'in sync' with their peers in the tertiary referral facilities in choosing expensive and newer drugs, even in the absence of clear indication, was worrying . This also points to the fact that guidelines don't work in isolation in certain facilities; they should be universal for them to work effectively.

The high compliance to guidelines also comes with additional financial burden to the patients if medicines are in short of supply at the health facilities. The front line medications, such as ACE-Inhibitors, are often more expensive than calcium channel blockers or diuretics. In the absence of free drug supply, it indicates that patients would be forced to purchase expensive drugs from private pharmacies. Further, many of the Medical Officers tended to prescribe expensive ARB-inhibitors instead of ACE-Inhibitors, which are among the front line anti-hypertensive medications. These facts reinforce the requirement of promoting rational use of guidelines in clinical practice.

The organisational culture also played an important role in the implementation of the intervention. For example, the work culture in the Indian health system is more task-oriented than output-oriented. Therefore, the Medical Officers, without any hesitation, were able to pressure the NCCs to assist them in attending other patients as well, which, in turn, reduced the time NCCs spent with hypertension and diabetes patients. This led to a dilution of patient counselling activities in OPDs where the NCCs were sharing the space along with the Medical Officers.

The implementation of the intervention faced several set-backs in setting-up of referral care for patients. The specialist clinics at the RH Solan were originally planned to serve as referral centres for the remaining OPDs of CHCs. Accordingly, an advanced clinical management guideline was developed for diabetes management with the inclusion of HbA1c investigations on par with most recent guidelines. For this purpose, a point – of – care device for HbA1c was installed at the district hospital laboratory as HbA1c investigation was not available there. Cartridges for the devices were provided free of cost to run the investigations at a subsidised rate to the patients. However, the lab technician was not willing to operate the machine, even after providing repeated training, citing the reason that the device was faulty. However, the technicians from the device manufactures confirmed that it had no defects and additionally provided a new device to the lab. The reluctance could have been due to an unwillingness to undertake additional job responsibilities or resistance from local private labs that ran the risk of losing business. Hence, the specialist clinics were unable to use DSS with an advanced algorithm that relied on HbA1c values for diabetes management. Another reason for failure to develop referral care was that the patients preferred to go to nearby tertiary care hospitals, such as IGMC Shimla or PGI Chandigarh, which had good facilities. Furthermore, an effort to link the patients with their respective sub-centres at the community level, for

follow-up care, using Smartphone technology, was also abandoned due to the heavy workload of the health workers in the community. Given these failures, it is worth looking for better alternatives to set referral care at CHCs, such as setting-up weekly specialist clinics for people with disease complications who require specialist care.

Transfer and postings of Medical Officers was an unanticipated event that affected the implementation of the intervention. During six months of the intervention, three trained Medical Officers got transferred and were replaced by three new Medical Officers. The NCCs faced difficulties with the new doctors until they were oriented and trained to deliver the intervention. Two of the new doctors would not allow the nurses to conduct screening and blood pressure measurements in their clinic, due to their perception that such tasks were unnecessary and they thought that the nurses were intruding into their territory of clinical decision-making. One of the Medical Officers even shouted at the NCC for conducting blood pressure measurement of patients and was not satisfied with her explanation about the ongoing intervention at the CHC. The new Medical Officers were trained individually at the hospital, after which only the doctors started cooperating with the NCCs.

At the CHCs, equipment such stethoscopes, BP apparatus, weighing scales and stadiometers are supplied only occasionally. The doctors bought BP apparatus and stethoscopes of their own and the equipment for the use of other staff was in bad shape. As part of the intervention, all the OPDs were supplied with new equipment, including Omron electronic BP monitors. However, within a week, the Medical Officers refused to use the electronic BP monitors, citing that they observed wide variations in blood pressure reading. Although it was explained to the doctors that variations in blood pressure was natural, they were reluctant to use the BP monitor. We also noticed that electronic blood pressure monitors required frequent replacement of batteries to ensure the accuracy of reading, which added to

the cost and additional effort by the NCC to purchase and replace the batteries. In addition, the expensive electronic BP monitors were prone to theft. Because of these reasons, it was decided to use ordinary mercury Sphygmomanometers instead of electronic BP monitors.

Several such contextual challenges as those described above shaped the delivery of the intervention at the CHCs in multiple ways. Thus, the assumptions on 'stability' of the environment across the facilities proved wrong while piloting the intervention in a real-world context and provided insights for attempting a larger phase three control trial.

9.4 The crucial role of the Nurse Care Coordinator

The evaluation of the implementation found that the intervention was feasible and acceptable to both the healthcare team and patients. The major reason for favourable results was the additional manpower – a trained Nurse Care Coordinator - deployed at the OPDs and dedicated to deliver most functions in the intervention. The new NCCs partially or fully addressed the manpower shortage at the OPDs of the hospitals. The choice of 'nurses' as additional manpower seemed to have worked in multiple ways. The nurses demonstrated high acceptance from Medical Officers as well as patients in their role as a care coordinator. Their ability to assist Medical Officers in additional clinical duties played a major advantage in getting acceptance to the intervention from Medical Officers. The Medical Officers admitted that the assistance from the NCCs was translating into a reduction in workload for them. Further, it could be inferred from the narratives of the Medical Officers that, due to heavy workload, guidelines and decision-support tools alone may not have improved the services from the health facility, pointing to the important role played by the NCCs in the intervention. However, the NCCs faced several difficulties at the CHCs in delivering the intervention. They were unable to cope with the workload when the number of patients

attending OPDs exceeded 60 a day, as they were asked by the physician to help him/her in attending patients with other diseases as well. Most facilities were lacking adequate space to accommodate even a single NCC. Moreover, the laboratory services and equipment supplied were insufficient to support the delivery of quality care. These realities have great implications for the implementation of NPCDCS in a country which envisages establishing an NCD clinic at the CHCs, with the appointment of a Medical Officer, two nurses, one counsellor and a data entry operator. The NPCDCS will fail to deliver if it compromises the proposed manpower (particularly nurses) with optimal opportunities for skill-building and facilities as per Indian Public Health Standards.

9.5 Reflections on acceptance of the intervention by patients

The intervention, during its course of implementation, gained attention from the patients as a dedicated service for hypertension and diabetes. The recognition can be solely attributed to the new cadre – Nurse Care Coordinator. Compared to Medical Officers, NCCs were easily accessible to patients and they have started asking questions about their health problems directly to the NCC, which is an indicator of acceptability of the intervention to the patients. The intervention did not entail any difficulties/ additionalities/conditionalities to the patient, including payment, procedural delays to enrolment, other requirements, etc. Further, patients were willing to cooperate for opportunistic screening when the purpose was explained to them. The patients did not have any major discomfort arising from the intervention, other than increase in the patient waiting time for additional clinical measurements and attending the patient counselling services.

The financial burden to patients arising out of adherence to lifelong medications is a major concern. Many studies in India have documented the heavy financial burden arising from

diabetes [54, 172, 173] and hypertension [174, 175] care in India. We found that the drug supply was sufficient to cover only 10% of the requirement. However, two promising developments occurred recently: the Drug Price Control Order, 2013 which aims to reduce the price of drugs by 60%, and the recent High Level Expert Group Report on Universal Health Coverage for India (HLEG on UHC), constituted by the Planning Commission of India, which recommended the Government of India to develop manpower and build infrastructure for providing universal health coverage for the citizens. Further, it has also recommended provision of free essential medicines at public health facilities, with an increase in the public procurement of medicines from 0.1% to 0.5% of GDP to ensure universal access to essential drugs, thereby greatly reducing the burden on private out-of-pocket expenditures and increasing the financial protection for households [72]. Chronic disease control programs would require such vital initiatives to ensure access and quality of care from the public healthcare system.

9.6 Reflections on developing a DSS for use in primary care settings

Considerable effort has gone into developing a Smartphone-based DSS tool that could be used for promoting guideline-based practices at CHCs. It has helped the healthcare team to conduct patient evaluation in a structured manner and also served as an electronic health record. The healthcare team were taken into confidence, and efforts were taken to include their viewpoints while developing the DSS and its components. The experience from developing the DSS provides some important points to which future researchers should give importance when attempting such experiments. We found that a touch-based interface was far better for the users than QWERTY keyboards. Iterative development and refinement of the DSS is inevitable during the initial development phase and, hence, a longer trial phase is required. Further, close interaction with the users for their feedback on revising the DSS is

essential to make the system fool proof. The data elements to be captured in the DSS need to carefully identified and prioritised before developing the system. Higher number of data elements requires the healthcare professionals to spend more time on the DSS and will negatively affect its acceptability and feasibility. The mPower Heart DSS ended up cutting down a third of the data elements (from 36 to 23) to make it user-friendly. A fool proof data back-up plan for the central server databases is central to deployment of the software to avoid data loss. Data losses could result in demotivation of users and risk their non-cooperation. Periodic training of the users would be required to ensure that the DSS is properly used.

9.7 Meaning of the findings and why they are important

There has been a greater recognition of NCDs, such as hypertension and diabetes as a major health challenge, in developing countries, including India. The approach at primary care level for tackling these diseases is to prioritise identifying and treating people at high risk of NCDs or with an already established disease, which has the potential to avert millions of deaths in the short-term [24–26] and has been identified by WHO as one of the best buys for NCDs in its global status report on non-communicable diseases, 2011 [27]. Evidence to support the appropriateness of interventions at primary care level for the prevention and management of NCDs has been reiterated in several reports [24–27]. The mPower Heart project intervention was conceived, developed and implemented precisely to address the needs at primary healthcare level. The piloting of the mPower Heart Project demonstrates that a trained non-physician health cadre, with the support of a decision-support tool, could carry out three major functions at the out-patient clinics: opportunistic screening, clinical evaluation with the help of decision-support tool, and counselling services for therapeutic lifestyle changes. The new cadre was also found to ease the workload of Medical Officers and find greater acceptance among them. Impact of the intervention on clinical outcome was also promising,

documenting a large reduction in the mean blood pressure and blood glucose level of the patients, although a comparison arm was not available. The use of an intervention package has resulted in greater adherence to clinical guidelines, as observed in a cluster randomised trial of a CVD risk management intervention in China and Nigeria. [176] This achievement assumes significance because the intervention was carried out in health facilities which were in short of supply of medicines and other support facilities. More importantly, these results demonstrate the enormous potential for task-shifting of diagnostic and therapeutic functions, at least partially, from physicians to less-specialised, non-physician health cadres as a solution to improve access and quality of chronic disease care in India. International experiences also favour task-shifting, as demonstrated in a Cochrane review which found similar outcomes in clinical indicators, process of care and resource utilisation or cost between the groups when nurses and physicians were compared in primary healthcare services provision [76]. Lack of prescription power for the nurse cadre would be a limitation in India. However, studies conducted in India and Pakistan have shown that primary health workers were able to reliably and effectively assess cardiovascular risks in a primary healthcare setting [177]. Hence, it is worth exploring such innovative approaches to expand the access to chronic disease care with the help of the nurse cadre in India in primary care settings. Further, the components of the mPower Heart intervention are similar to the approach recommended by WHO as a *'Package of Essential Non-communicable Disease Interventions for Primary Health Care in Low-Resource Settings',* which include early detection of NCDs and their diagnoses using inexpensive technologies, non-pharmacological and pharmacological approaches for modification of NCD risk factors and affordable medications for prevention and treatment of NCDs. [178]

During pre-intervention, health facility assessment exercise and the post-intervention assessment, insufficient skills and knowledge to provide chronic disease care was expressed by the healthcare workforce as a major concern. Lack of in-service training opportunities and absence of incentives to attend continued medical education programmes were additional concerns. The current training curricula of both medical and para-medical professionals are inadequate to equip them to provide chronic disease care. Therefore, the medical and para-medical training programmes in India need to be reoriented to address these training gaps. In addition, in-service training opportunities should also be provided by the health department to build the skills of the existing workforce.

The results from this study reinforce the concerns about a huge unmet need for hypertension and diabetes care in primary care settings. The fact that 19% of the out-patients aged 30 and above were newly detected with hypertension and/or diabetes, along with an equal number of diagnosed cases (18%), at the CHCs indicates that a large number of patients with hypertension and or diabetes go undiagnosed, even after reaching the primary facilities for healthcare in India. This alarming situation warrants the need for interventions for effective diagnosis and control of hypertension and diabetes in primary care settings.

During the intervention period, large reduction in systolic blood pressure was observed at the third month of follow-up (13.1+/-13.8 mmHg) in 2080 patients. The reduction in blood pressure observed was similar (13.1 +/- 16.2 mmHg) at six months, although only 415 patients achieved sixth-month follow-up. The reduction observed was similar to some of the previous studies which have reported the findings of nurse-led interventions in hypertension patients [108, 115]. Similar reduction (16.9 mmHg) was observed in the intervention arm of another ongoing cluster randomised trial of a community health worker-led intervention for reduction of cardiovascular risk in high-risk subjects in the neighbouring state – Haryana

(unpublished data from a recently concluded trial). The mean blood glucose reduction observed in diabetes patients was also high. The mean reduction observed at the third month of follow-up was 33.7 +/-49.9 mg/dl while the reduction was 56.8+/-72.3 mg/dl at the sixth month of follow-up. The baseline values of the diabetes group were very high and this could be the reason for the large reduction in fasting glucose values. On a longer follow-up, these observations could follow regression to mean and the larger reduction observed in systolic blood pressure and blood glucose level could level-off. Further, due to time constraints, six months and longer follow-up could not be achieved to address these limitations.

We did not have a dedicated lab support for the study and relied on lab reports from either the hospital or from private labs that patients brought during their follow-up visits. Since variations occur at random, the inter-laboratory variations in fasting glucose values need not be substantially affecting the above estimates, although the precision may be reduced. These results are particularly encouraging, given the fact the intervention was piloted in facilities with limited capacity. Thus, the favourable effect observed in the process and clinical outcomes favours the intervention package to be tested in a pragmatic control trial.

The intervention also highlights the need for use of technology for chronic disease care. The opportunistic screening at six OPDs, over a period of eight months, identified 5086 subjects with either hypertension or diabetes, which translates to managing long-term follow-up of 848 patients from a single OPD. This necessitates the need for technology, not only for decision-support for the healthcare team, but also for short messaging service (SMS) reminders to promote patient education, compliance and self-care. Several studies carried out in developed nations have proved that technology support could improve health outcomes in diabetes and hypertension care [161, 179].

9.8 Limitations of the study

There were certain limitations to this study in its findings. Because of the lack of interest from the government and limited resources available for the study, a control arm could not be added to the study. Further, this study was a pilot to develop an intervention, and was not fully-equipped to assess the effectiveness of the developed intervention on health outcomes. The limited number of out-patient clinics and healthcare teams involved in the development of the intervention and piloting could be another drawback, as the developed intervention might require further customisation or modification in other Indian states.

The Nurse Care Coordinators were employees of the mPower Heart Project and, therefore, their compliance to ensure the delivery of the intervention could be largely affected by the close monitoring system which was in place throughout the project, which may not have been achieved in the case of regular government employees.

In the study, the follow-up visits were voluntary and the follow-up rate observed at the third month was 64% for hypertension patients and 54% for diabetes patients. The sixth month follow-up rate could not be calculated, as the last patient enrolled in the sixth month of the project would qualify for their sixth month visit at the twelfth month of the project. Although short-term follow-up rates tend to be higher compared to long-term follow-up rates, this estimate could be a realistic one, as no effort was made to artificially increase the follow-up by calling the patients over the telephone to remind them to come for their follow-up visits. A reason for achieving higher reduction in the blood pressure and blood glucose in the patients could be the low-follow-up rate, as people with higher compliance came for the follow-up visit.

Although there was support for the project from the top health administration, the larger issues, such as insufficient drug supply and lack of laboratory facilities and manpower, could not be addressed. The full potential of the pilot intervention could have been evaluated had such support systems also been in place. However, the current assessment provides a real-world scenario as the Indian health system is yet to have sufficient resources in place for all support systems. It could be argued that the developed intervention does not merit passing to the next stage of a controlled trial, given the shortcomings in the health system capacity. However, India is transforming with high economic growth and there is greater interest in increasing public spending in the health sector and the NPCDCS is proposed to cover the entire nation by 2017. Hence, a controlled trial of the newly developed intervention will provide rich input to the NPCDCS in tailoring the capacity-building process in various Indian states. More importantly, the evidence gap in implementation of interventions in chronic disease care in India is a major concern. Given that the demand for healthcare is going to increase over time, hand-in-hand with enhanced care provision, determining the essential elements of intervention is vital in order to inform the newer strategies, programmes and delivery of more cost-effective measures to control hypertension and diabetes. Hence, it is important to attempt controlled trials of newly developed interventions for hypertension and diabetes care in primary care settings. Moreover, available research indicates that significant public health gains could be achieved if even the basic elements of non-communicable disease interventions were available at primary healthcare level [178].

Another limitation of this study was that most of the IDIs were conducted by myself, who was the Project Coordinator of the mPower Heart Project. This could have brought bias in the interpretation of the results. However, close monitoring by my PhD supervisors helped minimise the bias in the interpretation. Further, this study did not attempt a cost-benefit

analysis of the intervention, which is another drawback. The reason for not including this component was the uncertainty in the evolution of the various components of the intervention and its natural course during implementation. Therefore, a judgement on feasibility and scalability the intervention package was made without considering the cost of the intervention and the benefits derived.

9.9 Strengths of the study

This research work is the first of its kind to develop a context-specific intervention package for hypertension and diabetes in India. The development of the intervention followed the pathways of developing complex intervention, as recommended by MRC [180], with the use of mixed methods (use of observation, in-depth interviews and quantitative methods) during all the stages of the study, for collecting data from all the stakeholders of the intervention, thereby incorporating multiple viewpoints in the analysis and interpretation. Further a conceptual framework was followed for the entire research work, which will serve as a key resource for future research work in this domain. Although the study only included five CHCs and the RH Solan for developing and piloting the intervention package, the out-patient clinics of these facilities were catering to large numbers of patients. Over a period of six months, the CHCs had 56,814 OPD visitors and RH Solan had another 23,334 OPD visitors, and the opportunistic screening was conducted on a total of 18,222 eligible participants. These facilities were more or less similar to a typical CHC in India, which faces similar constraints in capacity; thus, it can be concluded that that the study was carried out in a 'real world scenario' and the study findings are robust.

This formative research work provides an assessment of the internal dynamics and actual operations while piloting a hypertension and diabetes intervention package in a primary care

setting in order to understand its strengths, weaknesses, feasibility and scalability. Very few studies have attempted formative research for developing chronic disease care interventions. Carefully planned formative research that assessed the detail, the context, content and the delivery of the intervention, prior to starting, have obviated some of the pitfalls in intervention delivery in HIV/AIDs [181], diabetes [182, 183], overweight/obesity [184] and new-born care practices [185]. The outcomes of this research require further validation in a controlled trial. Further, the findings from this study are likely to advance knowledge on developing intervention for chronic disease care and scaling-up a strategy to overcome barriers to care. Such approaches, if found to be effective and cost-effective, will have the potential to positively impact the healthcare of millions of Indians and will have wider applicability for other developing countries.

Chapter 10: Conclusions and recommendations

This research work has demonstrated the huge unmet need for hypertension and diabetes care in Indian primary care settings and the deficiencies in the capacity of the health system to address this gap in care. A Smartphone decision-support enabled, Nurse Care Coordinator-led intervention package, developed through a formative evaluation process, was found to be feasible and acceptable for primary care settings in India. The intervention package needs to be evaluated in a controlled trial for its efficacy and effectiveness on health outcomes in the next step. The newly developed intervention package assumes greater importance in the backdrop of greater commitment from the Government of India to expand the National Programme for the Prevention and Control of Cancer, Diabetes, Cardiovascular disease and Stroke to all districts in India by 2017. The expansion of the programme could be modelled on the newly developed intervention package to address the gaps in manpower, supplies and facilities to ensure greater access and quality of care in India's primary care system.

10.1 Next steps

This research work raises several other research questions to be answered relevant to chronic disease care in India:

1. How to develop a context-specific, integrated care delivery model for chronic diseases in Indian primary care settings?
2. How to integrate the decision-support tools for chronic diseases with those of other most common morbidities in order to reduce the workload of the primary care workforce?

3. What are the modalities to promote evidence-based medicine uniformly across private and public care providers?
4. How to develop feasible and scalable screening and follow-up care for chronic disease through community participation in primary care settings?
5. How to translate healthy lifestyle messages at primary care level through community participation?

10.2 Recommendations

The findings from this study offer some important recommendations for health policy making in India

1. It is important to invest in primary care infrastructure to address the growing challenge of chronic diseases in India. In addition, development of human resource in healthcare, particularly para-medical professionals, is equally important, with an effort to reorient their training curriculum to deliver chronic disease care
2. Task-shifting and task-sharing needs to be attempted to expand the access to chronic disease care in primary care settings
3. Evidence-based practices need to be enforced and encouraged among both private and public care providers
4. The access to affordable medicines needs to be ensured to reduce out-of-pocket spending and to improve compliance to medications.
5. The use of information and communication technologies needs to be promoted to improve quality of care

10.3 Outcome of the mPower-Heart Project

Since March 2014, the Wellcome Trust has funded the Public Health Foundation of India to conduct a cluster randomised trial (I contributed to the writing of this grant application) which aims to evaluate and develop a commercially-viable business model of a Smartphone/tablet-enabled NCD care package for primary care facilities in India under the 'Affordable Technology Development Scheme', which will make use of Smartphones and tablet computer devices for the use of healthcare teams. The intervention tested in this trial will rely on the mPower-Heart Intervention developed in this thesis work. Further, a research proposal, of which I am a Co-Investigator, on a large cluster randomised trial to evaluate the effectiveness of mPower Heart intervention on incidence of the composite outcome of major adverse cardiovascular events (MACE) - i.e. non-fatal Myocardial Infarction (MI), stroke, or cardiovascular death in the intervention group compared to usual care group at three years follow-up is currently in the third stage of review with the Global Health Trial Scheme of the Medical Research Council, UK. I wrote a grant proposal to the Indian Council for Medical Research (ICMR) as Co-Investigator, to conduct a phase-3 cluster randomised trial of the intervention package developed from this PhD work and this has been approved by the ICMR with a funding of five million Indian Rupees and will begin in March 2015. The results from the mPower Heart Project have been submitted to the Government of Himachal Pradesh and it has expressed considerable interest in the project and is currently planning to expand the project to a further two districts in the state.

Alongside the development of the intervention at five CHCs, a large cohort of 40,000 population, above the age of 20 years, was enrolled to develop the 'Solan Surveillance Study Cohort', which involves people residing in the six sub-centre areas adjoining each of the CHCs. The cohort was formed through a baseline questionnaire-based survey, along with

collection of clinical, anthropometric data and glucometer-based fasting glucose estimation. This activity was carried out to pilot an outreach and follow-up care for hypertension and diabetes from CHC by linking subjects detected in the baseline survey with the CHCs and sub-centres through community health workers. The cohort has currently enrolled 32,000 subjects.

The experience from the development of the decision-support system and the mPower Heart Intervention has been disseminated in the World Congress of Cardiology as well as in the Annual Steering Committee meeting of the 11 Centres of Excellence in Global Health worldwide, supported by the National Heart Lung and Blood Institute, USA, and the UnitedHealth Group, USA.

Deriving inputs from the literature review and from the experience of the mPower Heart Project, I have authored a section on *'Task-shifting and Technology'* in the upcoming, prestigious 3rd edition of the Disease Control Priorities Project.

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